

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
30 August 2001 (30.08.2001)

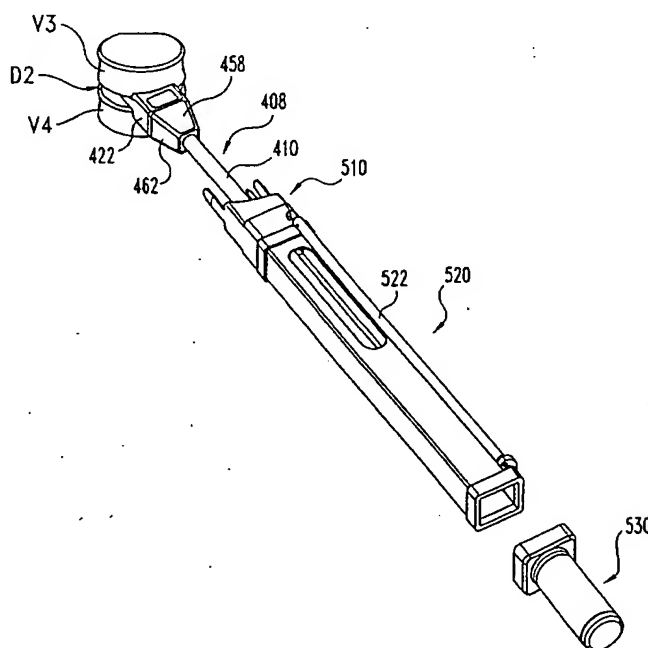
PCT

(10) International Publication Number
WO 01/62166 A2

- (51) International Patent Classification⁷: **A61B 17/16**, 17/17, 17/02
- (21) International Application Number: **PCT/US01/05500**
- (22) International Filing Date: 22 February 2001 (22.02.2001)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/184,107 22 February 2000 (22.02.2000) US
- (71) Applicant (for all designated States except US): **SDGI HOLDINGS, INC.** [US/US]; 300 Delaware Avenue, Suite 508, Wilmington, DE 19801 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **MCGAHAN, Thomas, V.** [US/US]; 4904 Harvest Fields Circle, Memphis, TN 38125 (US). **DERIDDER, Steven, D.** [US/US]; 6255 Skylight Drive, Bartlett, TN 38135 (US). **LANGE, Eric, C.** [US/US]; 2457 Calkins Road, Germantown, TN 38139 (US).
- (74) Agents: **LOWES, J., Andrew et al.**; Woodard, Emhardt, Naughton, Moriarty & McNett, Bank One Center/Tower, Suite 3700, 111 Monument Circle, Indianapolis, IN 46204 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- Published:**
— without international search report and to be republished upon receipt of that report

[Continued on next page]

(54) Title: INSTRUMENTS AND TECHNIQUES FOR DISC SPACE PREPARATION



(57) Abstract: A series of instruments (30, 80, 120, 210, 510, 550) are provided for direct-anterior and oblique-anterior disc space and end plate preparation. The instruments (30, 80, 120, 210, 510, 550) provide precise guidance for channel formation in the vertebral endplates by guiding rotating and bladed cutting instruments (122, 250, 580). Instrumentation (550) for oblique-anterior disc space preparation includes compound angulation to account for the angle of approach to the spine and the angulation between adjacent vertebrae. Methods and techniques for use of the instruments (30, 80, 120, 210, 510, 550) are also described.

WO 01/62166 A2



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INSTRUMENTS AND TECHNIQUES FOR DISC SPACE PREPARATION

5 CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims the benefit of commonly owned U.S. Provisional Patent Application No. 60/184,107, filed 22 February 2000, which is hereby incorporated by reference in its entirety.

10 BACKGROUND OF THE INVENTION

The present invention relates generally to instruments and techniques for preparing a site between two adjacent bony segments to receive an implant therebetween. More specifically, the present invention provides instruments for vertebral end plate preparation to receive interbody fusion devices or artificial disc
15 implants. The instruments and techniques of the present invention have particular application, but are not limited to, direct anterior or oblique-anterior approaches to the spine.

While implants of various types have been utilized throughout the body for various orthopedic bone applications, the present invention has particular
20 application to the field of preparing an intervertebral disc space to receive an interbody fusion device to create bony fusion or a spacer providing artificial disc functions. Such procedures may be necessary where the natural disc has degenerated or slipped resulting in pain and discomfort to a patient. The deterioration or movement of the disc often results in the two adjacent vertebral
25 bodies coming closer together. A common treatment is to surgically restore the proper disc space height to thereby alleviate the neurologic impact of the collapsed disc space. Typically, the damaged disc is removed and an alternative substance is inserted to maintain the proper height. While artificial discs have been developed and will likely continue to be developed that may be placed in the effected disc
30 space, present procedures often utilize a load bearing structure, either man-made or natural, to maintain the disc height and promote bony fusion between the adjacent vertebrae. Such techniques for achieving interbody fusion between adjacent vertebral bodies is well-known in the art, it will not be described further.

U.S. Patent No. 5, 772,661 to Michelson discloses methods and instrumentation for surgical correction of human thoracic and lumbar spinal disease from an anterior, lateral aspect of the spine. This patent discloses methods, techniques, and instruments for lateral placement of spinal implants. While the application does recognize that an approach from a lateral aspect of the spine in an area of lordosis may result in angulation between the end plates adjacent vertebra, this invention teaches only restoration of the proper angle between the vertebra. Subsequent preparation of the opening to receive an implant, however, is created by over cutting into the end plates of the adjacent vertebra disposed closest and potentially under preparing the end plates disposed farther apart. Thus, there is a need for end plate preparation which not only maintains lordotic angulation of adjacent vertebra, but also provides for substantial uniform preparation of the vertebral end plates to receive an implant.

International publication WO 98/04202 published February 5, 1998 discloses milling instrumentation and methods for preparing a space between adjacent vertebral bodies. This publication discloses utilization of a milling device to control the depth of penetration and field of cut of cutting instruments adapted to prepare vertebral end plates to receive an implant. However, as with earlier approaches to end plate preparation, this publication fails to teach instruments utilized to provide precise control over cutting depth, height, and angulation. Such drawbacks are particularly acute when it is considered that an oblique approach to the anterior spine may be necessary where patient anatomy does not permit easy direct anterior access to the spine.

Thus, there remains a need for improved instrumentation and techniques for disc space preparation. The present application is directed to those needs.

SUMMARY OF THE INVENTION

The present invention provides a variety of instruments for precision guided disc space preparation. While various approaches to the spine may make use of the instruments according to the present invention, the instruments are preferably adapted to a direct-anterior or oblique-anterior approaches to the spine. Additionally, the present invention contemplates novel methods for disc space preparation utilizing the guided instrumentation of the present invention.

One aspect of the invention includes a distraction window assembly provided with removable distraction flanges adapted to be removably received within the window assembly. In a preferred embodiment, a retaining clip is provided that releasably locks the flanges in position during use. In a further preferred aspect, the distraction window includes arcuate upper and lower bone engaging surfaces to provide intimate contact with the vertebral bodies.

In yet another aspect of the invention, a guide tube is provided for guiding instruments and implants there through. The guide tube acts to align the instruments and implants as well as protect surrounding tissue from damage during the various steps of a procedure. The guide tube includes an external locking mechanism operable to lock the guide tube to the window assembly from the proximal end of the guide tube. Preferably, the locking mechanism is operable without rotation of the guide tube. The external locking mechanism permits an unobstructed internal working channel and is operable without addition vessel retraction.

In still a further aspect of the present invention, a burr template is provided for mating engagement with the window assembly. The burr template may preferably include a guide housing having a cutting slot, a linkage assembly connected to the housing and a guide tube connected to the linkage. The guide tube is controlled to move laterally along the cutting slot while maintaining alignment of the cutting piece in the horizontal and vertical directions. Still more preferably, the guide tube is maintained at an oblique angle with respect to the housing. Additionally, the burr template may provide the capability of controlling the height of the burr cut into the vertebral body end plate. The burr template

assembly includes an incremental adjustment mechanism adapted to provide defined incremental adjustments of the height or depth of burr cutting into the end plate for precision milling of the end plates. In a preferred aspect, the burr template end face may be angled with respect to the distraction window such that a burr may be controlled to remove an angled surface of the end plate.

The present invention also includes a guide assembly for a bladed cutting instrument. The guiding assembly includes a slot adapted to receive a blade and a guide channel for maintaining alignment of the blade in the slot. In a preferred aspect, the slot and guide channel are disposed at an oblique angle permitting removal of a portion of a vertebra. In still a further preferred aspect, the guiding assembly is adapted for guiding instruments into the spine from an oblique-anterior approach. In this further aspect, the guiding assembly includes angulation to account for the oblique angle approach to the spine and compounding angulation to create the desired angle of the removed vertebral bone.

The present invention further contemplates a distractor for an oblique-anterior approach to the spine. In one preferred aspect, the distractor includes a substantially straight leading portion and an angled leading portion. Still further, it is preferable for maintaining or establishing angulation between adjacent vertebrae that the distractor have a head with a tapered portion oriented at an angle with respect to the longitudinal axis of the distractor. In one preferred embodiment, the offset is approximately 30 degrees.

The invention further contemplates a distraction window configured for oblique engagement to the spine. In one preferred aspect, the bone engaging surfaces are arcuate and including a leading portion extending more distally than a trailing portion. In still a more preferred embodiment, the distraction window includes distraction flanges configured to maintain angulation between adjacent vertebrae. The flanges preferably include a taper oriented at an offset with respect to the longitudinal axis.

In still a further aspect of the invention, a chisel adapted for oblique cutting of the vertebra is provided. The chisel comprises a first straight cutting edge and a second angled cutting edge. In a preferred aspect, the chisel further includes a third angled cutting edge shorter than the first angle portion.

The present invention further contemplates a method of disc space and endplate preparation from an anterior approach to the spine as further described and disclosed herein. Still more preferably, the anterior approach is from an oblique angle to the spine. In this aspect, the method includes gaining access to an oblique portion of the spine, inserting a distractor from an oblique angle and engaging a distraction window from the oblique angle. A cutting guide may then be engaged with the distraction window and the endplates may then be prepared from the oblique angle. In a preferred aspect, the endplates are prepared to include a taper between adjacent vertebrae.

10 These and other objects of the present invention will become apparent from a review of the accompanying drawings and the detailed description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a distractor disposed between two adjacent vertebral bodies from a direct anterior approach to the spine.

Figs. 2a and 2b are a side and top view, respectively, of the distractor of

5 Fig. 1.

Fig. 3 is a perspective view of the drawing of Fig. 1 further including a guiding assembly according to another aspect of the present invention.

Fig. 4 is a perspective view of the guide assembly of Fig. 3 positioned adjacent the disc space and the distractor removed.

10 Fig. 5a is a perspective view of a distraction window according to one aspect of the present invention.

Fig. 5b is a top view of the distraction window of Fig. 5a.

Fig. 5c is a side view of the distraction window of Fig. 5a.

Fig. 5d is a cross-sectional side view taken along line 5d - 5d of Fig. 5b.

15 Fig. 6a is an exploded perspective view of an alternative embodiment of a distraction window according to another aspect of the present invention.

Fig. 6b is a side view of the distraction window of Fig. 6a.

Fig. 6c is a front view of the distraction window of Fig. 6a.

Fig. 6d is a top view of the distraction window of Fig. 6a.

20 Fig. 7a is a side view of a retaining shaft for use with the guide sleeve of the present invention.

Fig. 7b is an end view of the guide shaft of Fig. 7a.

Fig. 8 is a perspective view of a distraction window according to the present invention disposed between adjacent vertebrae.

25 Fig. 9 is an exploded perspective view of rotary cutting guide assembly according to another aspect of the present invention.

Fig. 10 is a perspective view of the rotary cutting guide of Fig. 9 in an assembled configuration.

Fig. 11a is a side view of the rotary cutting guide of Fig. 9.

30 Fig. 11b is a rear view of the rotary cutting guide of Fig. 11a.

Fig. 11c is a front view of the rotary cutting guide of Fig. 11a.

Fig. 11d is a bottom view of the rotary cutting guide of Fig. 11a.

Fig. 11e is a top view of the rotary cutting guide of Fig. 11a.

Fig. 12a is a partial cross-sectional top view of a guide tube according to another aspect of the present invention.

Fig. 12b is an end view of the guide tube of Fig. 12a.

5 Fig. 13a is a perspective view of a guide tube linkage according to the present invention.

Fig. 13b is an end view of the guide tube linkage of Fig. 13a.

Fig. 13c is a side view of the guide tube linkage of Fig. 13a.

Fig. 14 is a perspective view of an alternative guide tube assembly
10 according to the present invention.

Fig. 15a is a perspective view of a guide block according to the present invention.

Fig. 15b is a side view of the guide block of Fig. 15a.

Fig. 15c is a rear view of the guide block of Fig. 15a.

15 Fig. 15d is a front view of the guide block of Fig. 15a.

Fig. 15e is a cross-sectional side view taken along line 15e – 15e of Fig. 15d.

Fig. 16 is a perspective view of a cutting blade guide assembly according to another aspect of the present invention.

20 Fig. 17a is a side view of the guide block of Fig. 16.

Fig. 17b is a rear end view of the guide block of Fig. 16.

Fig. 18a is a top plan view of a chisel blade configured for use with the guide block of Fig. 16.

Fig. 18b is a side view of the chisel blade of Fig. 18a.

25 Fig. 19a is a perspective view of an implant insertion assembly disposed adjacent a vertebral body.

Fig. 19b is an enlarged perspective view of the implant insertion assembly according to Fig. 19a.

Fig. 20a is a top plan view of an implant according to the present invention
30 disposed adjacent a prepared vertebral body.

Fig. 20b is a perspective view of the implant and vertebral body of Fig. 20a.

Fig. 21 is a perspective view of a distractor disposed between two adjacent vertebral bodies from an oblique anterior approach to the spine.

Figs. 22a through 22c are bottom, side and top views, respectively, of the distractor of Fig. 21.

5 Figs. 23a through 23d are top, rear end, front end and partial cross-section side view, respectively, of the distractor head of Fig. 21.

Fig. 23e is perspective side view taken along line 23e-23e of Fig. 23a.

Fig. 24 is a perspective view of a distractor and guide tube assembly according to a preferred aspect of the present invention.

10 Fig. 25 is a perspective view of the guide tube assembly of Fig. 24 disposed between adjacent vertebrae.

Fig. 26 is a perspective view of the distraction window of Fig. 25.

Fig. 27a through 27e are side, top, perspective, rear end, and front end views, respectively, of the distraction window of Fig. 26.

15 Fig. 28 is a perspective view of the distraction window and a guide block according to another aspect of the present invention.

Fig. 29 is a perspective view of a guide block assembly and chisel.

Fig. 30a is a side view the guide block of Fig. 28.

Fig. 30b is a front end view of the guide block of Fig. 30a.

20 Fig. 30c is a rear end view taken along line 30c-30c of Fig. 30a.

Fig. 31a is a side view an alternative guide block.

Fig. 31b is a front end view of the guide block of Fig. 31a.

Fig. 31c is a rear end view taken along line 31c-31c of Fig. 31a.

Fig. 32 is a top view of a chisel blade according to the present invention.

25 Fig. 33 is a side view of the chisel blade of Fig. 32

Fig. 34a is a perspective view of a guide tube and implant inserter according to the present invention.

Fig. 34b is an enlarged top view of the a portion of Fig. 34.

Fig. 35 is a perspective view of a vertebra and implant.

30 Fig. 36 is an alternative perspective view of the implant and vertebra of Fig.

35.

Fig. 37 is another perspective view of the implant and vertebra of Fig. 35.

Fig. 38 is a top view of a depth gauge in combination with a distraction window according to another aspect of the present invention.

Figs. 39 a and b are a top view and side view, respectively, of the depth gauge of Fig. 38.

5 Fig. 40 is a top view of a depth gauge in combination with a distraction window according to another aspect of the present invention.

Fig. 41a and 41b are a top view and side view, respectively, of the depth gauge of Fig. 40.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein, being contemplated as would normally occur to one skilled in the art to which the invention relates.

The present invention relates to instruments and methods for gaining access to a disc space between adjacent vertebral bodies, distracting the disc space to a desired height, preparing the disc space to receive an implant to maintain disc space height and angulation, and a method for inserting an implant into the prepared disc space. More specifically, while methods and instruments disclosed in the present application may have application in other areas of the spine or the body, it is specifically contemplated that the present instruments and method may be utilized in an anterior approach to the spine for implantation of various implant devices. Still more specifically, the present invention contemplates a direct anterior approach to the spine for implant placement as well as an anterior-oblique approach to the spine for disc space preparation and implant placement. It will be understood that an anterior-oblique approach to the spine may be desirable in certain areas of the spine where a direct anterior approach is difficult or impossible because of patient anatomy. The term implants in the present application is used in a broader sense to encompass both load bearing implants constructed of man-made materials, as well as load bearing implants formed of naturally occurring materials. Further, implants contemplated to be used with the present invention may include those intended to promote fusion between adjacent vertebra as well as artificial disc replacements. Implant inserters and specific implants are disclosed in U.S. Provisional Application entitled "INSTRUMENTS AND IMPLANTS FOR

MULTI-DIRECTIONAL INSERTION OF A VERTEBRAL SPACER," filed February 22, 2000, which is incorporated herein by reference in its entirety.

Referring now to Fig. 1, there is shown a partial spinal column consisting of vertebra V1 and vertebra V2 separated by a disc space D. It will be understood that access to disc space D is obtained by known surgical techniques and will not be described further herein. With the disc space D exposed, distractor 8 is positioned adjacent disc space D from a direct anterior approach. With respect to the view of Fig. 1, the X axis represents the anterior to posterior direction, the Y axis extends laterally, while the Z axis extends in the superior to inferior direction. As shown in Fig. 1, distractor 8 is inserted substantially parallel to the X axis. The position of distractor 8 in terms of anatomical position is substantially parallel to the sagittal and axial planes. Distractor 8 includes an elongated shaft 10 having a proximal end with a tool adapter 12 to receive a tool handle (not shown) and a distal end having a distraction head 14.

Referring to Figs. 2a and 2b, distraction head 14 further comprises opposing tapered leading surfaces 20 and 24 adapted to engage and spread the vertebrae as the surfaces are advanced into the disc space D. A guiding fin 18 is centrally disposed on distraction head 14. Guiding fin 18 has a height greater than tapered leading surfaces 20 and 24 as well as the overall height of distraction plug 16 such that guiding fin 18 may extend into the vertebral bone and guide the distractor into the desired position. The use of a guiding fin on a distractor is further disclosed in U.S. Patent Application Serial No. 09/418,741, which is incorporated herein in its entirety. Distraction plug 16 may take many known configurations including having tapered surfaces adapted to establish and maintain desired angulation between adjacent vertebrae. Further, distractor head 14 includes an arcuate bone engaging surface 26 and an opposing bone engaging surface on the bottom side, each adapted to engage the anterior portions of the respective upper and lower vertebral bodies.

In use, distractor 8 of Fig. 1 is disposed adjacent disc space D. Force is applied to shaft 10 to urge distractor head 14 into disc space D. As distractor head 14 advances into disc space D tapered leading surfaces 20 and 24 engage end plates E1 and E2, respectively urging vertebra V1 and V2 apart and maintaining

the distraction height by disposing the rest of distraction plug 16 within disc space D.

Referring now to Figs. 3 through 5d, there is shown a guide tube assembly adapted to be received over distractor 8 of Fig. 1. Guide tube assembly includes a distraction window 30 and a selectively coupled guide tube 32 with a removable guide cap 34. Referring more specifically to Figs. 5a-5d, distraction window 30 includes a working channel 45 configured to slidably receive centering block 22 of distractor 8. Extending distally from distraction window 30 is distraction holder 36 and opposing distraction holder 40. The distraction holders are adapted and configured to extend into the disc space D and engage end plates E1 and E2 to maintain the distraction obtained with distractor 8. Further, each of the distraction holders includes an external taper on its leading surface adapted to urge tissue to the exterior of the window and away from working channel 45. Distraction holders also include bone engaging surfaces, such as ridges 47 and 49 shown in Fig. 5c with respect to distraction holder 40, to inhibit dislodgment once positioned in the disc space. Additionally, distraction window includes arcuate bone engaging surfaces 42 and 44 adapted to engage the arcuate anterior portions of V1 and V2, respectively. Preferably, a spike 38 extends from bone engaging surface 42. Spike 38 is intended to penetrate vertebra V1 to provide additional stability to distraction window 30. Working channel 45 is interrupted by annular shoulder 46 marking the transition from the proximal portion 51 of larger dimension to the smaller dimensions of the distal working area 53 of distraction window 30. The distal working area 53 includes slightly tapering side walls. Distraction window 30 also includes a recess 48 on its upper surface.

Guide tube 32 includes a substantially rectangular working channel 62 adapted and configured to correspond with the proximal dimensions of working channel 45 of distraction window 30. While a rectangular working channel is disclosed in the present application, it will be understood that it is contemplated that working channels having substantially circular, oval, figure 8 or any other cross-sectional configurations may be utilized for disc space preparation and implant insertion. Guide tube 32 includes a front flange adapted to engage the proximal portion of distraction window 30. Guide tube 32 also includes retaining

assembly 54 that may be utilized to selectively couple guide tube 32 to distraction window 30. Referring to Fig. 4, retaining assembly 54 includes an outer shaft 64 coupled to guide tube 32. An inner shaft 60 extending along the length of outer tube 64. A finger lever 56 coupled to the proximal end of inner shaft 60 and a retaining foot 58 disposed on the distal portion of inner shaft 60. Inner shaft 60 is shown in more detail in Figs. 7a and 7b. The position of inner shaft 60 with respect to outer shaft 64 is maintained by pin 68 extending into annular groove 70.

An alternative version of a distraction window assembly is shown in Figs. 6a-6d. Distraction window assembly 80 includes selectively coupled distraction holders 82 and 84. It will be understood that distraction holders of various heights and angulations may be utilized with distraction window body 81 thereby providing a reduced number of window assemblies that must maintained in a sterilized condition for use by the operating staff. Distraction holders 82 and 84 may be quickly inserted or changed to meet the various demands of a particular surgery simply by removing retaining clip 86.

Distraction holder 82 includes a pair of opposing dove tail projections 98 and 100. A corresponding channel 92 is formed in distraction window body 81. Channel 92 includes a pair of opposed dove tail recesses 94 and 96 adapted to matingly receive dove tail projections 98 and 100, respectively. Retaining groove 104 extends on the upper portion of distraction window body 81 as well as along the sides of the distraction window assembly. Retaining groove 104 extends into channel 92 and in a similar fashion with respect to the retention of distraction holder 84. The intersection of channel 92 and 93 with retaining groove 104 creates openings 102 and 106, respectively. Groove 83 is formed on distraction holder 82 such that when disposed within channel 92 groove 83 is substantially aligned with slot 102. Distraction holder 84 is configured in substantially similar manner to mate with channel 93 and includes a similar retaining groove to align with slot 106. With distraction holder 82 disposed within channel 92 with the proximal portion abuttingly received against end wall 108, retaining ring 86 may be positioned within groove 104 thereby extending a portion of retaining ring 86 into groove 83 to hold distraction holder within the distraction window body 81.

Distraction window body 81 further includes an upper and lower projection 90 and 80, respectively. Projections 90 and 80 further include bores 91 and 89, respectively, configured to receive pins that may extend into the vertebra to further retain the distraction window assembly in relation to the vertebral bodies. Further, pins extending through bores 91 and 88 tend to maintain arcuate vertebral bone engaging surfaces 114 and 116 in intimate contact with the anterior portions of the vertebral bodies. Thus, distraction window assembly 80 defines a working channel 112 for access to the disc space and portions of the upper and lower vertebral bodies.

Distraction window 30 may be coupled to guide tube 32 by initially bringing guide tube 32 into a butting engagement with distraction window 30 such that flange 50 surrounds at least a portion of distraction window 30. Lever 56 may then be rotated to cause retaining foot 58 to rotate into recess 48 on distraction window 30. With retaining foot 68 extending into recess 48, distraction window 30 and guide tube 32 are thereby removably coupled to one another. Referring now to Fig. 3, the guide tube and distraction window assembly may then be advanced over distractor 8 with the distraction window assembly 30 guided into place by engagement with centering block 22 of distractor 8. Cap 34 may be positioned over flange 52 and force applied to the cap, such as by hammering, to advance distraction holders 36 and 40 into the disc space and pin 38 into the bone of the vertebra. Once the guide tube and distraction window assembly have been properly positioned, cap 34 may be removed and a handle attached to distractor 8 at coupling 12. Once a handle is attached to coupling 12, distractor 8 may then be forcibly removed from the disc space leaving the guide tube and window assembly positioned as shown in Fig. 4. Lever 56 of retaining assembly 54 may then be rotated in an upward direction thereby causing retaining foot 58 to rotate out of recess 48 on distraction window 30. With retaining foot 58 positioned out of recess 48, guide tube 32 may be disengaged from distraction window 30. Thus, as shown in Fig. 8, distraction window 30 retains its position in the disc space and adjacent the anterior portions of vertebra V1 and V2 with distractor holders 36 and 42 engaging end plates E1 and E2 to maintain the disc space height and angulation

established by distractor 8. As shown in Figure 8, portion 72 of vertebra V1 and portion 74 of vertebra V2 are accessible through distraction window 30.

Referring now to Figures 9-15e, there is shown a rotating tool guide adapted for utilization with a distraction window 30 according to the present invention. Guide assembly 120 includes a guide housing 125 shown in greater
5 detail in Figs. 15a-15e. Guide housing 125 includes an insert end 124 configured to be received within proximal portion 51 of distraction window 30. It will be understood that distal end 127 of guide housing 125 abuttingly engages wall 46 in distraction window 30. Further, the walls of insertion end 124 are configured to be
10 a substantially close fit with the walls defining proximal portion 51 of distraction window 30. Further, surface 123 of guide housing 125 is configured to engage the proximal most portion of distraction window 30. Thus, guide housing 125 is adapted to have insertion portion 124 matingly received within the proximal portion 51 of window assembly 30. Insertion end 124 is a substantially close fit
15 with the dimensions of proximal portion 51 such that there is little movement of the guide housing with respect to the distraction window in directions other than proximally toward the user.

Guide housing 125 further includes cutting window 128. In a preferred embodiment, particularly useful for fashioning vertebral end plates to establish
20 and/or maintain angulation between adjacent vertebra, upper surface 176 and lower surface 177 of cutting window 128 are disposed at an angle A1 with respect to the longitudinal axis 179. Flange 129 is disposed within cutting window 128 and may act as a bearing surface for elements of the guiding assembly. As further described herein, the angulation of cutting window 128 with respect to the longitudinal axis
25 179 permits end plate cutting and preparation at an angle desirable to maintain and/or establish an angular relationship between adjacent vertebrae. Further, guide face 126 and flange 129 are set at a corresponding angle A2 with respect to the longitudinal axis. It will be understood that the angulation of guide face 126 provides a side wall 142 that tapers between the upper surface 144 to a greater
30 thickness at bottom surface 146. Thus, guide face 126 and flange 129 provide a reference plane for the attachment of other guiding elements such that they may be maintained in the proper angular relationship with the angle of cutting window

128. Internally threaded bore 178 is defined in housing 125 and is disposed at an angle substantially equal to a angle A1. In a preferred embodiment, threaded bore 174 is disposed equidistant between sidewalls 142 and 143 such that it is substantially centered with respect to the lateral dimensions of guide block 125.

5 Guide assembly 120 further includes a guide tube 130 shown in greater detail in Figs. 12a and 12b. Guide tube 130 includes a through channel 131 having a proximal end with an internal chamfer 152 configured to guide and align a tool shaft as it is inserted. Further, internal channel 131 includes an annular flange 154 dividing areas of larger and small diameter of working channel 131. In a preferred
10 embodiment, guide tube 130 is interconnected by linkage 132 to a linkage post 156. Preferably, the interconnection between guide tube 130, linkage 132, and guide post 156 is substantially rigid and does not permit pivotal movement of one member with respect to the other. Guide post 156 further includes an axial bore 158 defining an internal thread. Another component of guide assembly 120
15 includes guide post 134 having an axial bore 164 extending there through. Preferably, guide post 134 is rigidly interconnected with linkage tube 160. Linkage tube 160 includes an axial bore 162 extending there through.

 Guide assembly 120 is assembled by placing linkage post 156 within bore 162 of linkage tube 160. Assembly screw 150 is then inserted with external
20 threads threadedly engaging the internally threaded bore 158. Head 170 is sized to be larger than bore 162 such that assembly screw 150 retains linkage. Assembly screw 150 may be tightened by a tool-engaging slot if desired. The interconnection between linkage post 156 and linkage tube 160 permits rotation of linkage tube about linkage post. Distal portion 133 of guide tube 130 is then
25 disposed within window 128 and guide post 134 is aligned with threaded opening 174 such that internal bore 164 is in substantial alignment with threaded bore 174. An elongated assembly screw with a shaft sufficient to extend through bore 164 is utilized to attach guide post 134 to housing 125. The connection between housing
30 125 and guide post 134 permits pivoting of guide post 134 about the shaft of assembly screw 148. Further, as shown in Fig. 11a, guide tube 130 and guide post 134 are disposed at an angle A1 with respect to the longitudinal axis 179 of

housing 125. Thus, guide tube is in substantial alignment with cutting window 128 and will be maintained in substantial alignment throughout the cutting process.

Referring to Fig. 14, an alternative embodiment of a guiding assembly according to the present invention is shown. Guiding assembly 185 includes a housing 125, guide tube 186 and linkage 187. A portion of guide tube 186 is received within linkage 187 as described above with respect to the embodiment of Fig. 9. Post 188 extends the length of linkage 187 and fixedly engages housing 125. Post 188 may be engaged to housing 125 by, but without limitation, threads, pinning, welding, adhesive, or any other suitable mechanism. Post 188 further includes a groove at its proximal end. Preferably, a snap ring 189 may be inserted into the groove to retain the linkage on post 188. Preferably, snap ring 189 is easily removed to permit disassembly. While a snap ring has been disclosed other removable connection mechanisms may be used. It is contemplated that the linkage and guide tube may be used with multiple housings having various angulations and heights.

Referring now to Figs. 9 and 10, guide assembly 120 may be inserted into distraction window 130 with insertion end 124 securely received within distal portion 51. In a preferred embodiment a burr may be received with the cutting bit 136 extending into channel 131 and substantially beyond channel 131 with the ability to engage and cut exposed vertebral bone or other tissues. Shaft 138 is substantially received within channel 131 with large portion 140 abuttingly engaging annular flange 154 to limit the axial extent cutting instrument 122 may extend within guide 120. Shaft 138 is sized to be a snug fit within channel 131 to provide precise guiding of the cutting bit 136. In a preferred aspect, cutting instrument 122 will further include a coupler 139 for attachment to a power source to drive cutting bit 136. Only a particular cutting instrument has been shown for use with the guide of the present invention. However, it is contemplated that other alternative cutting instruments, including hand operated instruments, may be utilized in combination with the guide assembly of the present invention, it being understood that the guide assembly 120 provides controlled cutting of angular surfaces with the angle of cut being substantially maintained over a large lateral distance. Further, guide tube 130 and the accompanying linkage not only maintain

the vertical angulation of the cutting instrument but also maintain the cutting instrument in a substantially fixed side-to-side angulation thereby limiting the potential for accidental penetration into tissues along the lateral extent of the disc space. More specifically, guide tube 130 maintains the orientation of cutting bit 136 substantially perpendicular both horizontally and vertically with respect to flange 129 and guide face 126.

Referring now to Fig. 16, there is another perspective view of distraction window 30 in combination with a cutting blade guide 210 and a cutting instrument 250. As previously discussed with respect to guide assembly 120, blade guide 210 includes an insertion end 224 configured for engagement with proximal portion of distraction window 30. Blade guide 210 includes a blade channel 214 defined by opposed surfaces 217 and 215. In a preferred aspect, opposed surfaces 215 and 217 are substantially parallel and extend at an angle A4 with respect to the longitudinal axis 219. In one embodiment, angle A4 is approximately 4 degrees. However, it is contemplated that angle A4 may vary between 0 degrees and 30 degrees depending on patient anatomy and the amount of bone to be removed. Blade guide assembly 210 further includes a guide channel 216 defined by opposed side walls 218 and 220 and lower guide surface 222. These surfaces also extend at an angle A4 with respect to axis 219. Guide assembly 210 also includes an internally threaded bore 230 and an enlarged external flange 226 having a surface 228 adapted to abuttingly engage the proximal edge of distraction window 30. Figs. 17a and 17b further disclose a tooling ball 225 utilized during the manufacturing process as a reference point for manufacturing the various angled surfaces of the guide assembly. It will be understood that tooling ball 225 is preferably removed after manufacture.

Referring now to Figs. 18a and 18b, cutting instrument 250 includes a blade 252, a stop 254 disposed on the proximal portion of blade 252, a shaft 256 interconnected with a handle 258. Blade 252 includes a cutting blade having a first leading blade 260, a first lateral cutting blade 261, and a second lateral cutting blade 262. Cutting blades 261 and 262 are preferably set with an angle A5 with respect to the longitudinal axis 263. In a preferred embodiment, A5 is approximately 30 degrees. Blade 252 further includes guiding rib 264 extending

substantially along the longitudinal axis of the blade and having a height substantially taller than the blade thickness. It will be understood that guiding rib is configured to slidably engage guide channel 216 formed in guide housing 210. Blade 252 further includes a stop 254 having a leading face 268 disposed at an angle A6 with respect to the longitudinal axis of the blade. Preferably angle A6 is between 80 and 100 degrees in a more preferred aspect is 94 degrees. Leading edge 268 is adapted to abuttingly engage the face of housing 210 to prevent further advancement of blade 252. The trailing edges of blade 252 include tapered surfaces 266 and 267 set at an angle A7, which preferably is 60 degrees. Blade 252 is attached to shaft 256.

Referring to Fig. 16, it will be understood that as cutting instrument 250 enters guide 210 the leading elements of blade 252 engage the exposed vertebral bone (see Fig. 8) and continue at the designated angle thereby removing a portion of the vertebral end plate at the desired angular relation. Viewing window 212 of housing 210 permits the user to remove the cutting debris and view the end plate to determine if preparation has been completed.

Referring to Figs. 38 through 39b, there is shown a depth gauge according to the present invention. Depth gauge 700 includes a shaft 702 interconnected with a depth blade 707. Depth blade 707 has an elongated portion 704, wide body portion having side walls 705 and 706, and proximal shoulders 708 and 710. Referring to Fig. 38, depth gauge 700 may be inserted into window 30 and into the disc space to visually evaluate the intended depth of cut into the vertebral endplates. Side walls 705 and 706 maintain alignment in window 30 while shoulders 708 and 710 are configured to engage the proximal end of window 30 to limit further advancement. With shoulders 708 and 710 engaged with window 30, elongated portion 704 approximates the distance for a given cutter depth. It will be understood that a variety of depth gauges may be provided to approximate various depths of bone removal.

Guided end plate preparation by both rotary cutting means and cutting blades has been disclosed in the foregoing description. It will be understood that the thickness of vertebral bone removed, the angle of the cut and the side-to-side movement (if any) is precisely controlled by the design of the guides. Guides

allowing varying incremental bone removal are contemplated to provide the ability to adjust endplate preparation depths without removal of the distraction window. Furthermore, controlled end plate preparation of the upper vertebral bone has been disclosed, it being understood that the guides may be rotated 180 degrees and
5 inserted into the distraction window for substantially similar preparation of the lower end plate.

After a disc space has been prepared including removal of the desired amount of end plate bone at the desired angle, an implant may be inserted through distraction window 30. Referring now to Figs. 19a and 19b, guide tube 32 is
10 preferably reattached to distraction window 30 as previously described. An insertion device 290 configured for insertion through the guide tube and distraction window may then be utilized. Insertion device 290 represents an example of such an insertion device. Implant inserter 290 includes an outer shaft 294, an inner shaft
15 296 having a threaded distal end and a thumb wheel 292 attached on a proximal end. The inner shaft is free to rotate within outer shaft 294. The distal end of the insertion device includes implant engaging surfaces 297, 298, and 299. It being understood that preferably surfaces 297, 298, and 299 have an angular relationship substantially matching the surface of the implant. Further descriptions of other
suitable implant inserters and implants are provided in Provisional Application
20 entitled "INSTRUMENTS AND IMPLANTS FOR MULTI-DIRECTIONAL INSERTION OF A VERTEBRAL SPACER," filed on February 22, 2000, and is hereby incorporated by reference in its entirety.

In use, the implant includes an internal bore and thumb wheel 292 is rotated such that externally threaded internal shaft 296 engages an internal bore on the
25 implant firmly positioning the implant against the implant engaging surfaces 297, 298, and 299. The implant and inserter advance through the guide tube 32 and through distraction window 30 until the implant is positioned in channel C2 prepared an end plate E2 of vertebra V2 and a corresponding channel of the end plate of the upper opposed vertebra. Implant 300 is retained in position between
30 distraction holding members 36 and 40 in the prepared disc space. In a preferred aspect, implant 300 is entirely disposed within the boundaries of vertebra V2 and is oriented to maintain proper angulation between adjacent vertebral bodies. The

relationship of implant 300 with respect to vertebra V2 is shown more clearly in Figs. 20a and 20b.

Referring to drawing Figs. 21- 39c, there are disclosed instruments and techniques for approaching the spine from an anterior-oblique direction. With respect to patient anatomy, the spine is approached in substantial alignment with the axial plane and at an oblique angle with respect to the sagittal plane. It is believed that precision guided techniques and instrumentation for an oblique-anterior approach to the spine have not been previously available.

Referring specifically to Fig. 21, a portion of the spine including two adjacent vertebrae V3 and V4 are shown with disc space D2 disposed between the adjacent vertebrae. The vertebrae are shown in a perspective view from a substantially anterior perspective. As the XYZ coordinate system illustrates, the X coordinate comes substantially out of the paper, the Y coordinate extends from left to right, and the Z coordinate extends from top to bottom of the drawing Fig. 21. A distractor 408 is shown disposed in disc space D2 and is oriented in the disc space along longitudinal axis 411. Reference line 413 is drawn substantially parallel to X-axis and forms an angle A10 with longitudinal axis 411. While it is contemplated that an oblique approach to the spine may be made at a variety of non-orthogonal angles, in a preferred aspect of the invention angle A10 is approximately 30 degrees.

Distractor 408 includes elongated shaft 410, a tool engaging end 412 adapted to engage a driving or retrieval tool and a distraction head 414 disposed on the distal end of shaft 410. Distractor 414 includes a centering block 422 and inclined surfaces on the proximal portion tending to align a guide sleeve with centering block 422. With respect to drawing Figures 23a-23e a tool ball 452 is shown. The tool ball 452 is utilized during the manufacturing process to insure proper alignment for the various machining operations. It is contemplated that the tooling ball will be removed from the finished product after the manufacturing process is substantially complete.

Referring now to Figs. 23a-e, the centering block 422 incline surfaces include upper surface 458 and opposed lower surface 460 combined with opposing side surfaces 462 and 466. Distraction head 414 further includes a leading edge

440 and an angled leading edge 442. As shown in Fig. 23a, angled leading edge 442 is disposed at an angle A12 with respect to leading edge 440. In a preferred embodiment, angle A12 is approximately 30 degrees corresponding to the oblique angle of approach to the anterior spine. Adjacent leading edge 440, distraction head 414 has a top tapered surface 434 and a bottom tapered surface 436. Similarly, adjacent angled leading edge 442 there is a top tapered and angled surface 438 and a bottom angled tapered surface 436. Angled surfaces 438 and 436 are formed in a plane extending substantially 30 degrees with respect to similar surfaces 434 and 432. Top tapered surfaces 434 and 438 lead to upper distraction surface 434 while lower tapered surfaces 432 and 436 lead to lower distraction surface 436. Upper distraction surface 444 terminates into upper bone engaging surface 428. In a similar manner lower distraction surface 446 terminates in bone engaging surface 426. Bone engaging surface 428, and in a similar fashion lower bone engaging surface 426, are defined by a concave arcuate surface based on an off center radius of curvature. Specifically, upper bone engaging surface 428 has a leading edge 468 extending more distally than trailing edge 470. In a preferred aspect, leading edge extends substantially 6mm more distally than trailing edge 470.

As shown in Fig. 23a, a slot 448 is formed through the leading portion of distraction head 414. Slot 448 is offset from side wall 456 by distance D10 and is offset from opposing side wall 454 by distance D11. In a preferred aspect, distance D10 is greater than distance D11 resulting in slot 448 being substantially off center with respect to the centerline of distraction head 414. A guiding fin 430 having a height greater than corresponding portions of distraction head 414 may be disposed in slot 448 and held in position by pins 450 extending there through. Guiding fin 430, shown in Figs. 22a-c, is adapted to engage the vertebral bone and cut a guiding channel through the bone to maintain the proper direction of distraction head 414 during the insertion process. Still further, a bore 466 is formed in the rear of distraction head 414 and is utilized for interconnection with shaft 410.

It is contemplated that instruments according to the present invention may be utilized from an anterior-oblique approach for distraction on the vertebra having

a non-parallel angular relationship. In this instance, establishing and/or maintaining the appropriate angular relationship between adjacent vertebra must be considered when approaching the disc space from an oblique angle. Thus, in one aspect of the preferred embodiment, upper distraction 444 and lower distraction surface 446 are disposed at an angle approximating the desired angular relationship of the vertebral disc space. While such angulation may vary from 0 degrees to 20 degrees throughout the spine, particular angles of 4 degrees to 12 degrees of angulation are often encountered in lumbar spinal applications. The angular relationship of the upper distraction surface 448 and lower distraction surface 446 is best shown in Fig. 23e and is indicated by angle A14. In this embodiment, A14 is approximately 8 degrees. Fig. 23e is a side view of Fig. 23a looking at an angle of approximately 30 degrees with respect to longitudinal axis 451. Thus, angulation A14 between the upper and lower distraction surfaces is oriented at approximately a 30 degree angle with respect to the longitudinal axis of the device such that as the instrument is inserted into the disc space from an oblique approach, the appropriate posterior to anterior angulation of the vertebral end plates may be accomplished.

Referring now to Fig. 24, a guide tube 520 and distraction window 510 coupled by a locking mechanism 522 may be slidably advanced along distractor 408. The locking mechanism between guide tube 520 and distraction window 510 is similar to that previously discussed with respect to the embodiment shown in Fig. 3 and will not be further described herein. As shown in Fig. 26, guide tube 520 may be removed to gain access to the disc space D2 and end plate E4 at portion 516.

Referring to Fig. 26, distraction window 510 defines an interior working channel 512 separated into a distal portion and a proximal portion 544 by internal flange 514. Distraction window 510 includes distraction projections 518 and 517 disposed on opposite sides of the device. Distraction projections 518 and 517 when adapted for use with lordotic angulation include a taper corresponding to the angle of distractor 408 oriented at a 30 degree angle with respect to the longitudinal axis 513. Further, distraction window 510 includes upper bone engaging surface 536 and lower bone engaging surface 538, each having a concave

engagement surface with an offset radius of curvature. The bone engaging surfaces 536 and 538 are adapted to engage the anterior portions of the upper and lower vertebrae respectively. As shown in Fig. 27b, upper bone engaging surface includes a leading 542 and a trailing portion 540. Leading portion 542 extends
5 approximately 6mm more distally than trailing portion 540 in a preferred embodiment. The extent that leading portion extends beyond the trailing portion depends on the oblique angle selected for access to the spine, the width of the window and the size of the vertebra to be engaged. Preferably, upper bone engaging surface 436 includes a spike 424 for projecting into the upper vertebral
10 body. As previously described, distraction window 510 includes a recess 526 for engaging a locking mechanism of guide tube 520.

Referring now to Fig. 28, there is shown the distraction window 510 disposed between vertebra V3 and vertebra V4. A guide block 550 having an insertion end 552 configured for engagement with proximal end 544 is also
15 disclosed therein. The details of guide block are more fully shown in Figs. 30a-c. Guide block 550 defines a blade guide 554 having an upper surface 668 and a lower surface 666. Specifically, the blade guide includes a guide channel 570 defined by a lower surface 588 and two opposed side walls 592 and 594. Guide block 550 further includes a visualization and working channel 556. Blade guide
20 554 proceeds at an angle from the front 557 to the back 559 at an angle of A13. Referring specifically to Fig. 30a, reference line 572 represents a line substantially parallel to the longitudinal axis of the guide lock and reference line 574 extends in a line substantially parallel to blade guide 554. Reference lines 572 and 574 are disposed at an angle of A13. In a preferred aspect, A13 may be approximately 3.5
25 degrees, however other angulations are contemplated as maybe desired depending on the anatomy of the spinal segment being treated.

Blade guide 554 is also oriented at an angle extending from side 556 to 553. Referring now to Fig. 30c, a front view of Fig. 30a viewed at an angle of approximately 3.5 degrees. Reference line 562 is substantially parallel to the top
30 surface 569 of block 550. Reference line 564 is substantially parallel to upper and lower surfaces 668 and 666, of blade guide 554. Reference lines 562 and 564 are disposed at an angle A17. In one preferred aspect, A17 is substantially 2 degrees.

In another preferred aspect, reference angle A17 is substantially 4 degrees. Other angles of side-to-side angulation are contemplated and will depend on the particular anatomy of the spine to be addressed. Thus, blade guide opening 554 is set at a compound angle including a front-to-back angulation and a side-to-side angulation. Guide block 550 further includes an internally threaded bore 578 adapted to receive a portion of a handle to hold the guide block. As with previous described embodiments, a tooling ball 560 is provided to provide a reference point for creating the various compound angle surfaces. The reference ball 560 is intended to be removed once the manufacturing process is substantially complete.

Referring to Figs. 31a-31c, guide block 595 is provided for preparing the bottom end plate. Guide block 595 is substantially a mirror image of guide block 550 and includes a blade guide opening 597 and guide channel 598 having angulation resulting in substantially mirror image guide blade slot when compared to guide block 550. The angle of guide blade from front to back is represented by A16 and is approximately 3.5 degrees. The angulation from side-to-side is represented by angle A15 and is approximately 2 degrees in a preferred embodiment shown in drawing Fig. 31c.

Referring now to Fig. 33, a cutting blade 586 is shown for utilization with the upper guide block shown in Fig. 30a-c. Guide blade 586 includes a guiding rib 610 extending above the surface of the guide blade. Guide rib 610 is adapted to be received within guide and channel 670. Blade 586 further includes a leading cutting edge 616, a large angled cutting edge 618, and a smaller cutting edge 620. Angled cutting edge 618 and 620 extend at a substantially 30 degree angle with respect to cutting edge 616. Large angled cutting edge 618 is approximately 3 times longer than cutting edge 620. A lower cutting blade or chisel (not shown) having substantially the mirror image of chisel 586 is provided for use in lower guide block 595 to prepare the lower vertebral endplate for receiving an implant. The lower cutting blade includes a guiding rib that is offset from the center line such that it will not fit in the upper guide block. Similarly, the lower guide block has a guiding channel that is offset from center line such that it may receive the lower cutting blade guide rib but not the upper cutting blade guide rib.

Referring to Figs. 40 through 41b, there is shown a further depth gauge suitable for use in the oblique approach to the spine. Depth gauge 800 includes a shaft 802 interconnected with a blade 804. Blade 804 includes leading edges 806, 808, and 810 approximating the geometry of the cutting edges of the chisels previously described. Blade 804 has a width defined by side walls 812 and 814. Shoulders 816 and 818 are formed on the proximal end of blade 804. Referring now to Fig. 40, blade 804 may be inserted into window 510 to evaluate the area of cut that will be performed with a particular dimension of chisel. Blade 804 may be guided laterally by engagement of side walls 812 and 814 with portions of window 510 and longitudinally by engagement of shoulders 816 and 818 with the proximal end of window 510. In this position, the surgeon may evaluate visually, through x-ray, or any other means, the area of bone intended to be removed. It will be understood that various length blades 804 may be provided to approximate various length chisels.

An implant inserter such as shown in Figs. 34 a and b is provided to advance an implant to the disc space. Inserter 650 is substantially as previously described with respect to the inserter of Fig. 19a. Implant inserter 650 includes an outer shaft 654 with an inner shaft disposed therein and having a thumb wheel 652 on the proximal for transmitting rotation force to drive the opposing threaded end of the inner shaft (not shown) into a corresponding opening in implant 670. Implant inserter 650 has modified implant engaging surfaces 656, 658 and 660 adapted to correspond to the surfaces of implant 670 disposed at approximately a 30 degree angle to the approach for grasping the implant. Implant 670 is sized and configured for advancement through guide sleeve 520 and distraction window 510 and placement in the disc space from an oblique anterior approach to the spine.

Referring to Figs. 35 through 37, the final placement of implant 670 in channel or cut C4 in vertebra V4 is shown. Posterior surface 672 is in substantial alignment with posterior portion 676 of vertebra V4. Similarly, anterior surface 674 is in substantial alignment with anterior portion 678 of vertebra V4. Further, the taper between the upper and lower bone engaging surfaces of implant 670, shown by angle A20, extends from the posterior to anterior portion with increasing height. Thus, implant 670 may maintain angulation between adjacent vertebra.

The present invention contemplates a method of guided disc space and endplate preparation from an oblique approach to the spine. The method is initiated by obtaining access to an oblique anterior portion of the spine. This includes well known approaches to the anterior of the spine as well as any required vessel retraction by previously known procedures. Once an oblique portion on the anterior spine adjacent the affected disc space is exposed, all or part of the disc material may be removed. A distractor 408 is then advanced into the disc space from an oblique angle to the spine. For applications where it is desirable to achieve or maintain angulation between adjacent vertebral endplates, distractor 408 may include a desired taper, extending at an angle corresponding to the oblique angle of approach to the spine, to establish the proper angulation. Referring to Fig. 24, after distraction an interconnected distraction window 510 and guide tube 520 are advanced over distractor 408. Distraction window 510 includes distraction flanges have tapering heights, when viewed at the oblique angle of approach to the spine, to maintain the angulation previously established by the distractor. The distraction flanges are advanced into the spine and the bone engaging surfaces of the distraction window are brought into close proximity to the anterior portions of the upper and lower vertebral bodies. With the distraction window properly position in and adjacent the disc space, distractor 408 is removed. Guide tube 520 may also be uncoupled from distraction window 510 and removed. The locking mechanism permits uncoupling from the proximal end of guide tube 520 thus limiting the need for additional vessel retraction adjacent distraction window 510 to permit a surgeon to access a locking mechanism.

The distraction window 510 provides a surgeon with clear access to the disc space and vertebral endplates. As shown in Fig. 40, a depth gauge may be inserted through window 510 to evaluate the depth and area of bony endplate to be removed. Further, distraction window 510 provides a platform for guided preparation of the vertebral body endplates. Referring to Fig. 28, a guide block 550 is slidably received in proximal portion 544 of the distraction window. Insertion portion 552 is configured for a relatively close fit with proximal portion 544, thereby limiting relative movement between the distraction window and guide block. If additional connection between the distraction window and guide block is

desired, a locking mechanism may be provided to releasably lock the guide block to the distraction window.

Referring to Fig. 29, a chisel 580 or other non-rotating cutting instrument is inserted into blade guide 554 of the guide block. In a preferred embodiment intended for preparing endplates with a desired angulation, the blade guide
5 includes a compound angular relation to the distraction window. Specifically, blade guide includes an oblique side-to-side angle as well as an oblique front-to-back angle. In a further preferred aspect, the cutting blade includes a guiding ridge 610 adapted to be received within guiding channel 670 thereby providing
10 additional control over the blade advancement.

The cutting blade is advanced through the upper blade guide and a corresponding portion of vertebral endplate is removed. The debris from the cutting procedure may be removed with the guide block still in place or the guide block may be disengaged from the distraction window and the debris removed.
15 Once the debris is removed, the endplate may be visually inspected. If the user desires the removal of additional endplate bone, a guide block permitting an incrementally greater amount of bone removal, typically in 1mm increments, may be substituted for guide block 550 and the cutting blade reinserted. Once the upper endplate is satisfactorily prepared, a lower guide block 595 may be inserted into
20 distraction window 510. A cutting blade cooperable with the lower guide block is inserted into blade guide 597 and utilized to similarly prepare the lower endplate.

Once the upper and lower vertebral endplates have been properly prepared with cuts or channels adapted to receive an implant, the guide blocks are removed from the distraction window. Preferably, guide tube 520 is reconnected to
25 distraction window 510. An implant is interconnected with an implant inserter and the implant is positioned through the guide tube and distraction window into the disc space. Despite the fact that the implant has been inserted from an oblique angle to the spine, the guided disc space preparation permits placement of tapered implant in the proper orientation in the disc space. The final implant placement
30 shown in Figs. 35 through 37 is comparable to the implant placement shown in Figs. 20a and b accomplished by a direct anterior approach to the spine. Thus, the present method of implant placement provides a new guided approach to the spine

that may be particularly useful where patient anatomy makes direct anterior or lateral approaches to the spine difficult and/or dangerous to patient health.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and
5 not restrictive in character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

1. A medical instrument for preparation of a disc space between adjacent vertebrae of a patient, comprising:

5 a burr assembly adapted to matingly engage a window assembly that is coupled to between the adjacent vertebrae, said burr assembly including a guide housing having a cutting slot defined therein, and a guide assembly pivotally linked to said guide housing, said guide assembly being adapted to guide a cutting piece in said cutting slot while maintaining alignment of said cutting piece.

10

2. The instrument of claim 1, wherein said guide assembly is constructed and arranged to guide said cutting piece at an oblique angle with respect to a sagittal plane of the patient.

15

3. The instrument of claim 1, wherein said burr assembly includes an incremental adjustment mechanism adapted to incrementally adjust cutting depth of said cutting piece.

4. The instrument of claim 1, further comprising said cutting piece
20 removably coupled to said guide assembly.

5. The instrument of claim 4, wherein said guide assembly angles said cutting piece to mill an angled surface on an end plate of one of the vertebrae.

25

6. The instrument of claim 4, wherein said cutting piece includes a shaft and a cutting bit provided at one end portion of said shaft, said shaft having a large portion to limit extension of said cutting piece into the vertebrae.

7. The instrument of claim 1, wherein said guide assembly includes a
30 guide tube having a through channel adapted to receive said cutting piece, said cutting slot having a flange portion in which a portion of said guide tube is received, said guide tube further including a linkage and a linkage post extending

from said linkage, said guide assembly further including a linkage tube pivotally coupled to said guide housing and said linkage post.

8. The instrument of claim 7, further comprising a snap ring attaching
5 said linkage tube to said guide post.

9. The instrument of claim 1, wherein said guide assembly maintains
angular alignment of said cutting piece during lateral movement of said cutting
piece.
10

10. The instrument of claim 1, further comprising said window
assembly matingly engaged to said burr assembly, wherein said window assembly
is adapted to attach to the adjacent vertebrae from an oblique approach with respect
to a sagittal plane of the patient.
15

11. A medical instrument for preparation of a disc space between
adjacent vertebrae of a patient, comprising:
a cutting blade guide adapted to matingly engage a window assembly that
is coupled to between the adjacent vertebrae, said guide having a blade channel
20 defined therein adapted to receive a cutting blade, said blade channel having a
guide channel adapted to receive a guiding rib on said cutting blade to maintain
alignment of said cutting blade.

12. The instrument of claim 11, wherein said guide has a working
25 channel defined therein adapted to allow removal of cutting debris.

13. The instrument of claim 11, further comprising said cutting blade
received in said blade channel.

14. The instrument of claim 13, wherein said cutting blade has a stop to
30 limit advancement of said cutting blade.

15. The instrument of claim 13, wherein said cutting blade has an angled cutting surface adapted to remove from an oblique approach with respect to a sagittal plane of the patient a portion with a substantially uniform depth from an endplate of one of the vertebrae.

5

16. The instrument of claim 15, wherein said guide includes a lower blade guide and said cutting blade includes a lower cutting blade, said guide channel of said lower blade guide being offset, and said guide rib of said cutting blade being offset to only mate with said guide channel of said lower blade guide.

10

17. The instrument of claim 11, wherein said guide is constructed and arranged to guide said cutting blade from an oblique approach with respect to a sagittal plane of the patient.

15

18. The instrument of claim 11, wherein said guide has a front portion and a back portion opposite said front portion, said guide further having a pair of opposing sides adjoining said front portion and said back portion, said blade channel being obliquely angled with respect to said front and back portions, and said blade channel being obliquely angled with respect to said opposing sides.

20

19. The instrument of claim 11, further comprising a depth gauge provided in said blade channel, said depth gauge being adapted to visually indicate an intended cutting depth of said cutting blade.

25

20. The instrument of claim 11, further comprising said window assembly matingly engaged to said guide.

30

21. A medical instrument for preparation of a disc space between adjacent vertebrae of a patient, comprising:
a distractor including a distraction head adapted to distract the adjacent vertebrae from an oblique approach with respect to a sagittal plane of the patient, said distraction head having a first leading edge and a second angled leading edge,

said second leading edge being obliquely angled with respect to said first leading edge, wherein said first leading edge and said second leading edge each have adjoining upper and lower tapered surfaces.

5 22. The instrument of claim 21, wherein said upper and lower tapered surfaces respectively adjoin upper and lower distraction surfaces.

 23. The instrument of claim 22, wherein said upper distraction surface terminates in an upper bone engaging surface, and said lower distraction surface
10 terminates in a lower bone engaging surface.

 24. The instrument of claim 23, wherein said upper and lower bone engaging surfaces are each defined by a concave arcuate surface based on an off-centered radius of curvature.

15 25. The instrument of claim 24, wherein said distractor further includes a shaft coupled to said distraction head, wherein said shaft has a tool engaging end adapted to engage a tool.

20 26. The instrument of claim 25, wherein said distraction head has a pair of opposing sidewalls adjoining said upper and lower distraction surfaces, said distraction head has an offset slot defined therein, wherein said slot is off center with respect to a centerline of said distraction head that parallelly extends between said sidewalls.

25 27. The instrument of claim 26, further comprising a guiding fin having a height greater than corresponding portions of said distraction head provided in said slot, wherein said fin is adapted to cut a guide channel in the vertebrae to maintain proper orientation of said distraction head during insertion.

30 28. The instrument of claim 21, further comprising an offset slot defined in said distraction head and a guiding fin having a height greater than

corresponding portions of said distraction head provided in said slot, wherein said fin is adapted to cut a guide channel in the vertebrae to maintain proper orientation of said distraction head during insertion.

5 29. The instrument of claim 21, further comprising a distraction window having a working channel defined therein, said distractor being provided in said working channel, said distraction window being adapted to engage the adjacent vertebrae from the oblique approach with respect to the sagittal plane of the patient.

10 30. The instrument of claim 29, further comprising a guide tube having a locking mechanism coupled to said distraction window.

15 31. A medical instrument for preparation of a disc space between adjacent vertebrae of a patient, comprising:
 a distraction window adapted to engage the adjacent vertebrae from an oblique approach with respect to a sagittal plane of the patient, said distraction window including a working channel defined therein and opposing distraction projections extending therefrom, said distraction window further including an
20 upper bone engaging surface and a lower bone engaging surface with each having a concave engagement surface with an offset radius of curvature.

 32. The instrument of claim 31, wherein said upper bone engaging surface includes a spike adapted to project into one of the vertebrae.

25 33. The instrument of claim 32, wherein one of said opposing distraction projections projects farther than the other.

 34. The instrument of claim 33, wherein said working channel has an
30 internal flange defined there around.

35. The instrument of claim 34, wherein said distraction window has a recess defined therein adapted to engage a locking mechanism.

36. The instrument of claim 35, wherein said upper bone engaging surface includes a trailing portion and a leading portion extending farther than said trailing portion.

37. The instrument of claim 31, wherein said distraction projections include distraction holders, said distraction window further including a retaining clip coupling said distraction holders to said distraction window.

38. The instrument of claim 31, further comprising a guide tube coupled to said distraction window, said guide tube having a locking mechanism, wherein said distraction window has a recess defined therein in which a portion of said locking mechanism engages.

39. The instrument of claim 31, further comprising a distractor provided in said working channel, said distractor being adapted to distract the adjacent vertebrae from the oblique approach with respect to the sagittal plane of the patient.

20

40. The instrument of claim 31, further comprising a burr assembly matingly engaged to said window assembly.

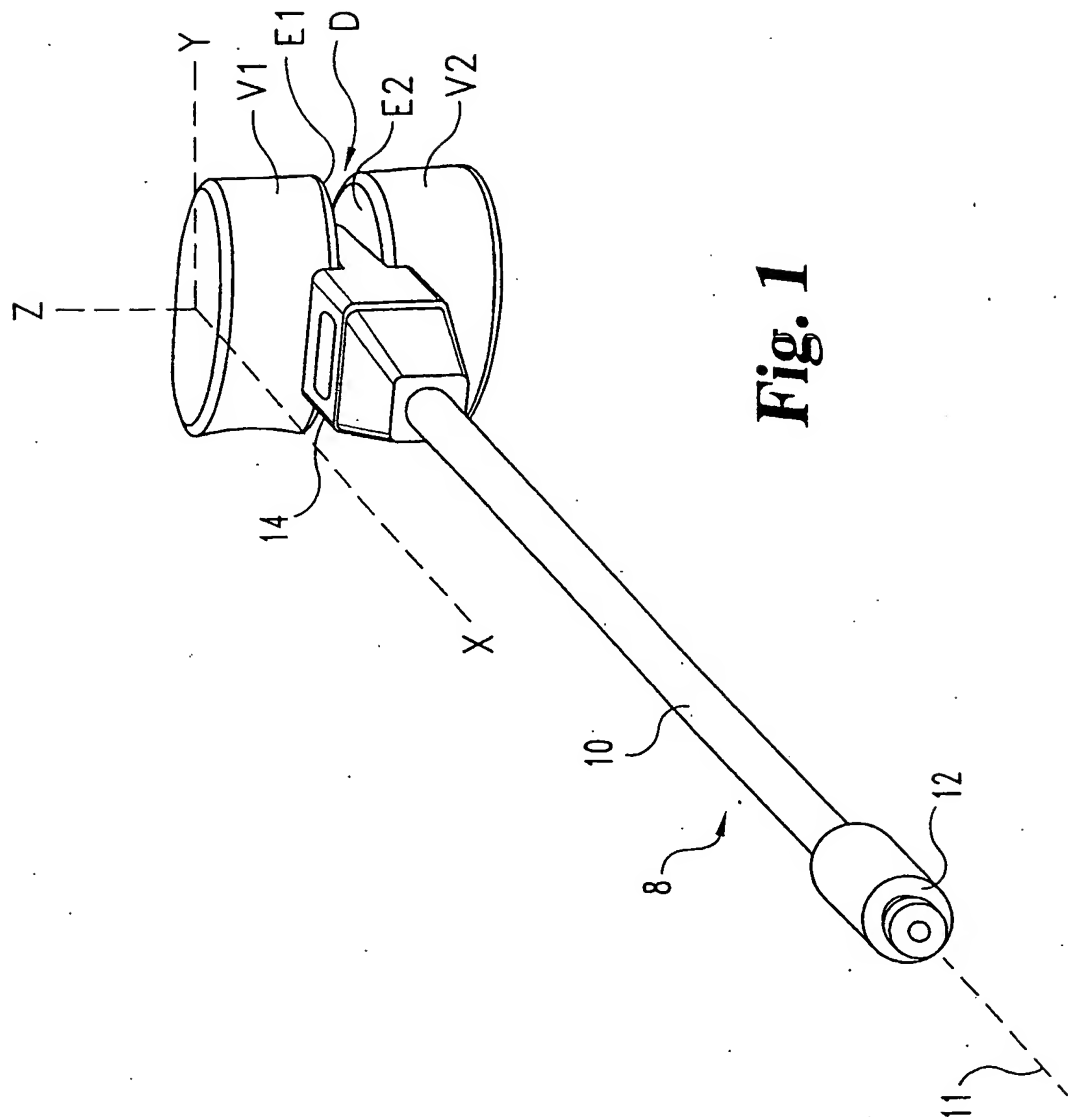
41. The instrument of claim 31, further comprising a cutting blade guide matingly engaged to said window assembly, said guide having a blade channel defined therein.

25

42. The instrument of claim 41, further comprising a depth gauge provided in said blade channel, said depth gauge being adapted to visually indicate an intended cutting depth of a cutting blade.

30

43. The instrument of claim 41, further comprising a cutting blade provided in said blade channel



2/41

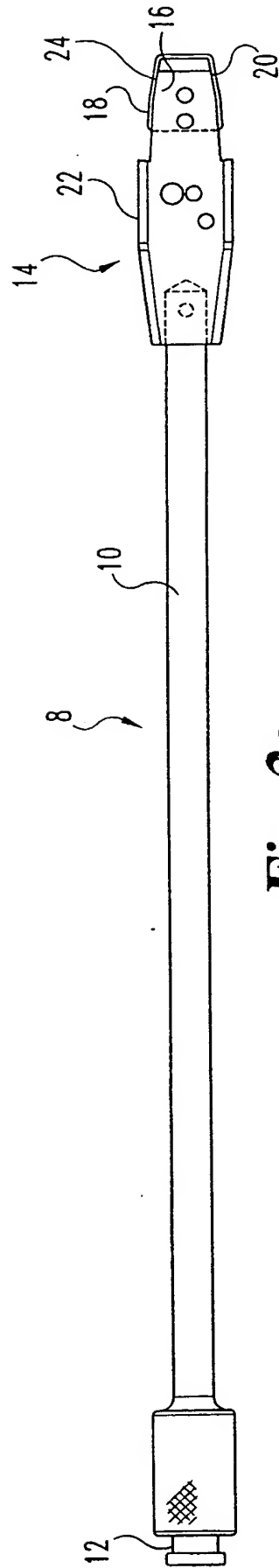


Fig. 2a

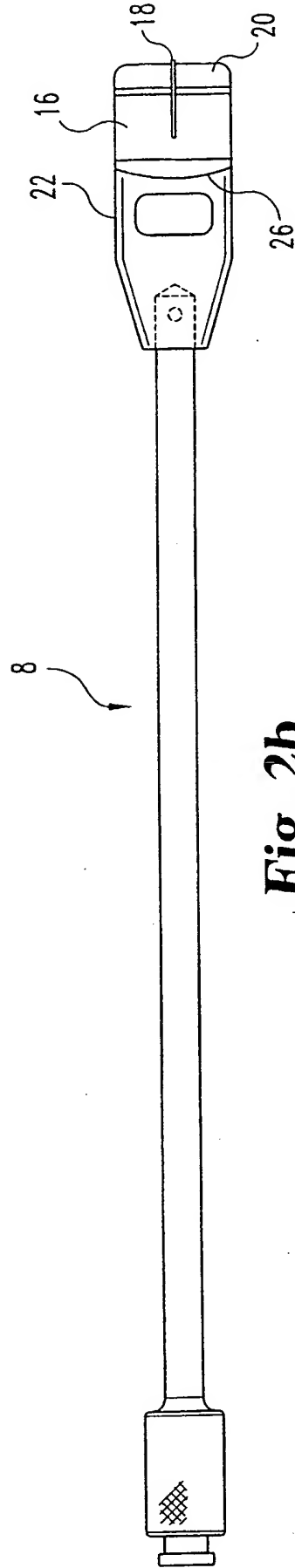
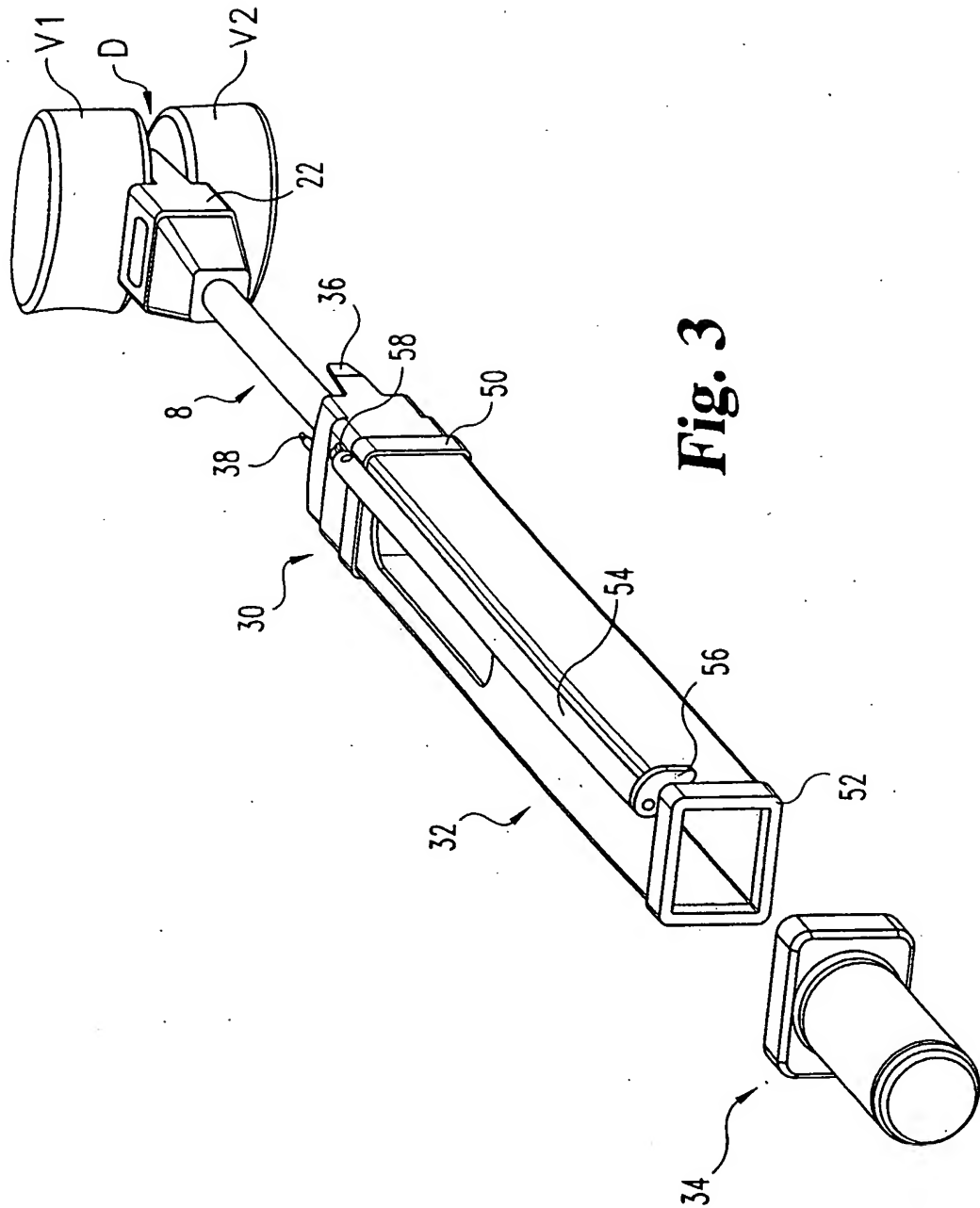


Fig. 2b



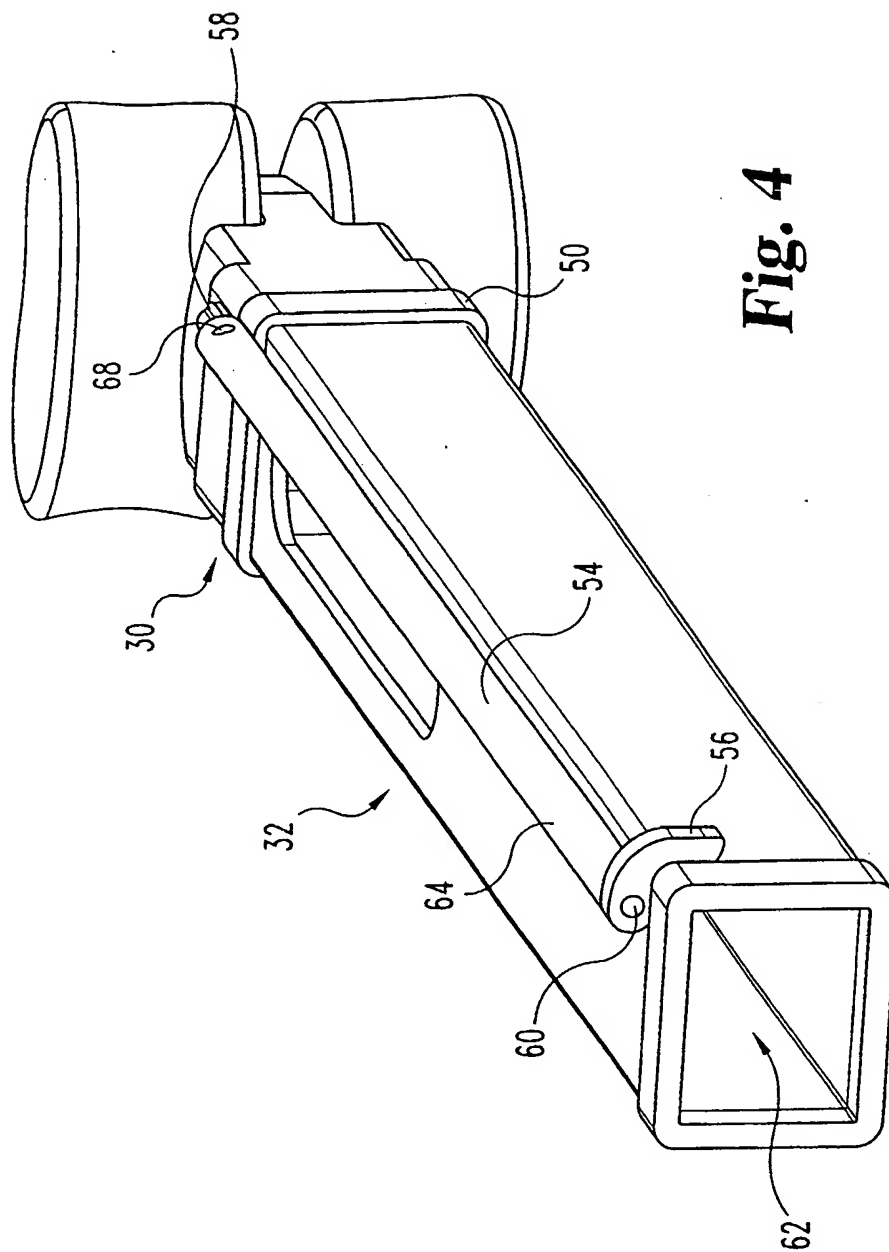


Fig. 4

5/41

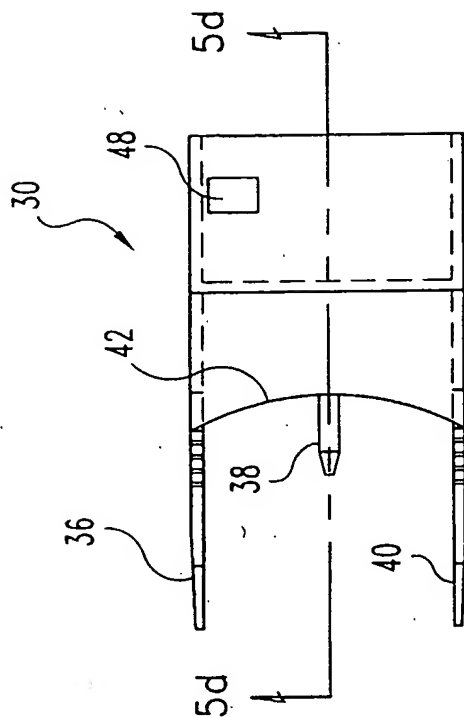


Fig. 5b

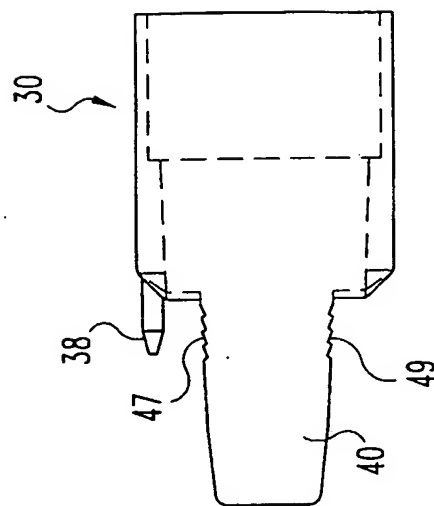


Fig. 5c

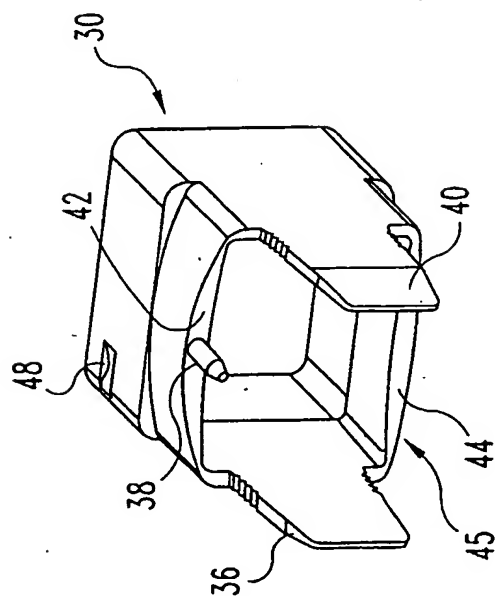


Fig. 5a

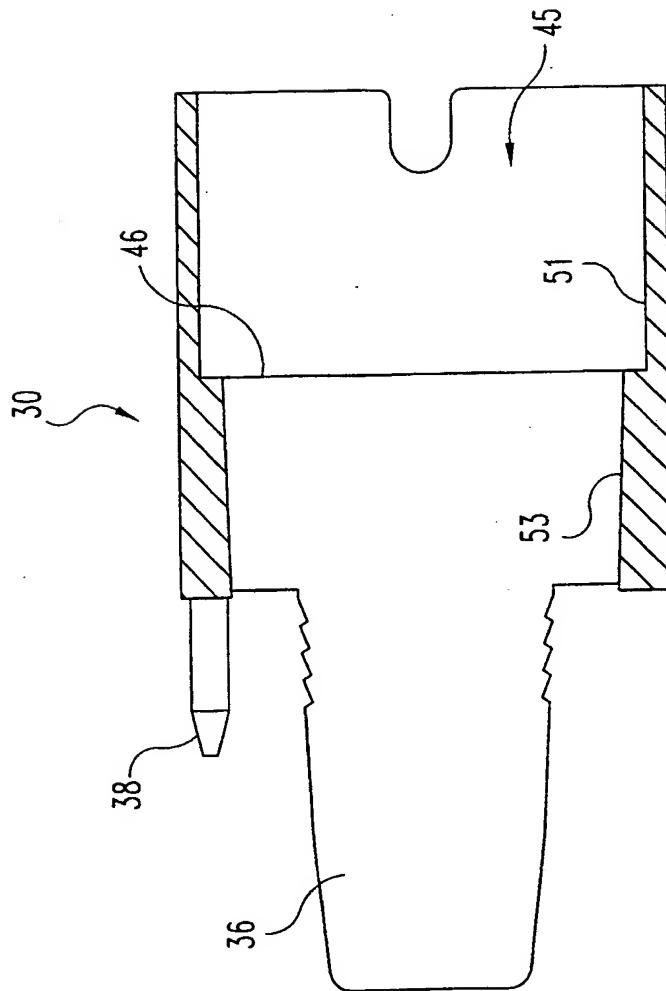


Fig. 5d

7/41

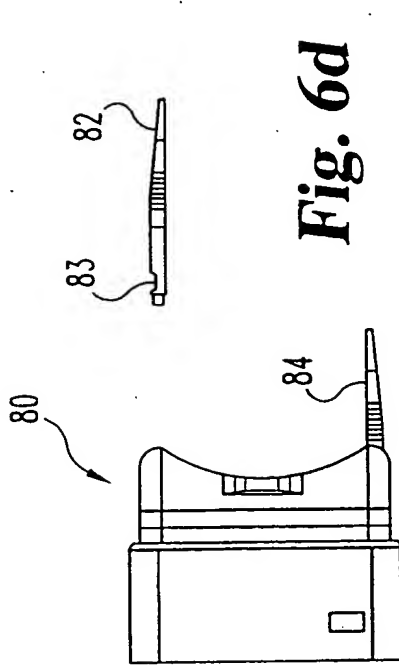


Fig. 6d

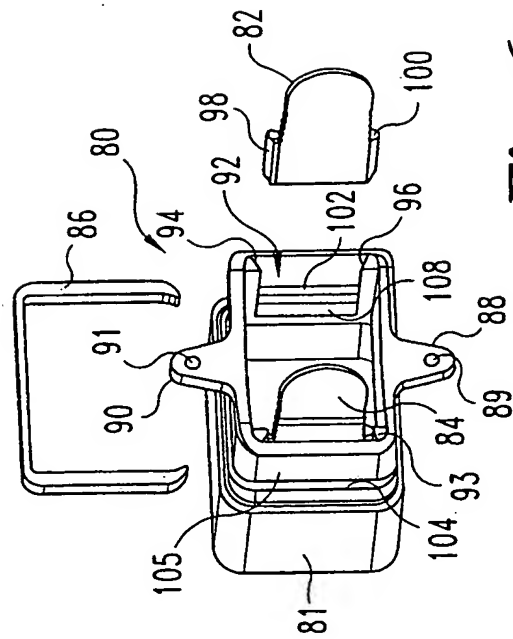


Fig. 6a

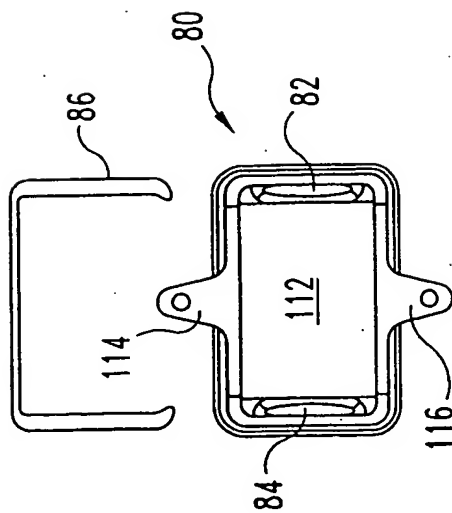


Fig. 6c

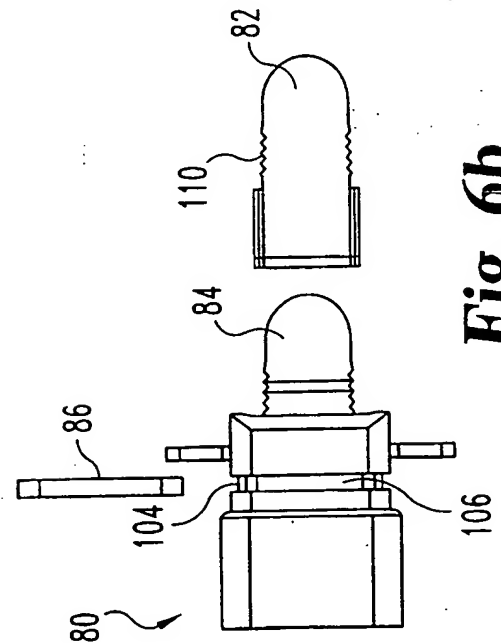


Fig. 6b

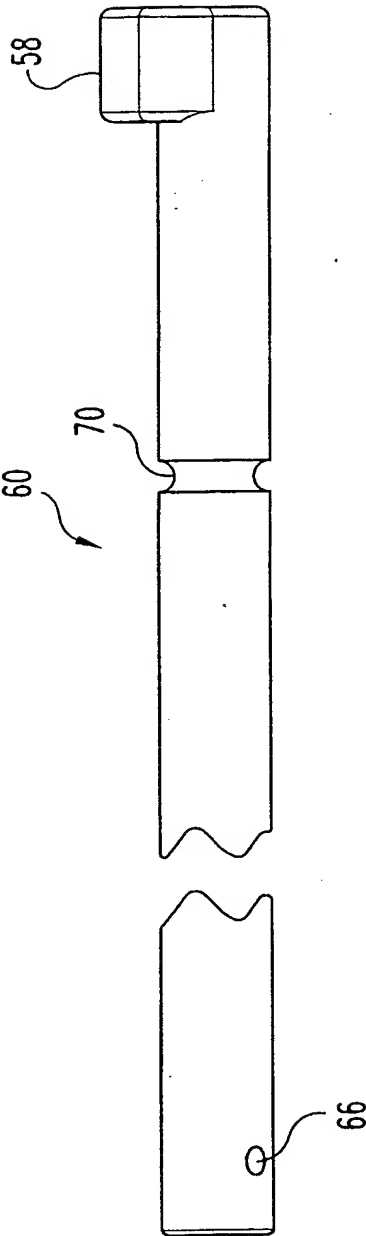


Fig. 7a

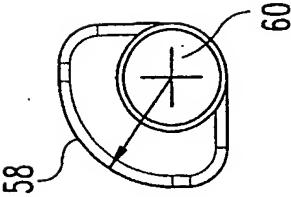


Fig. 7b

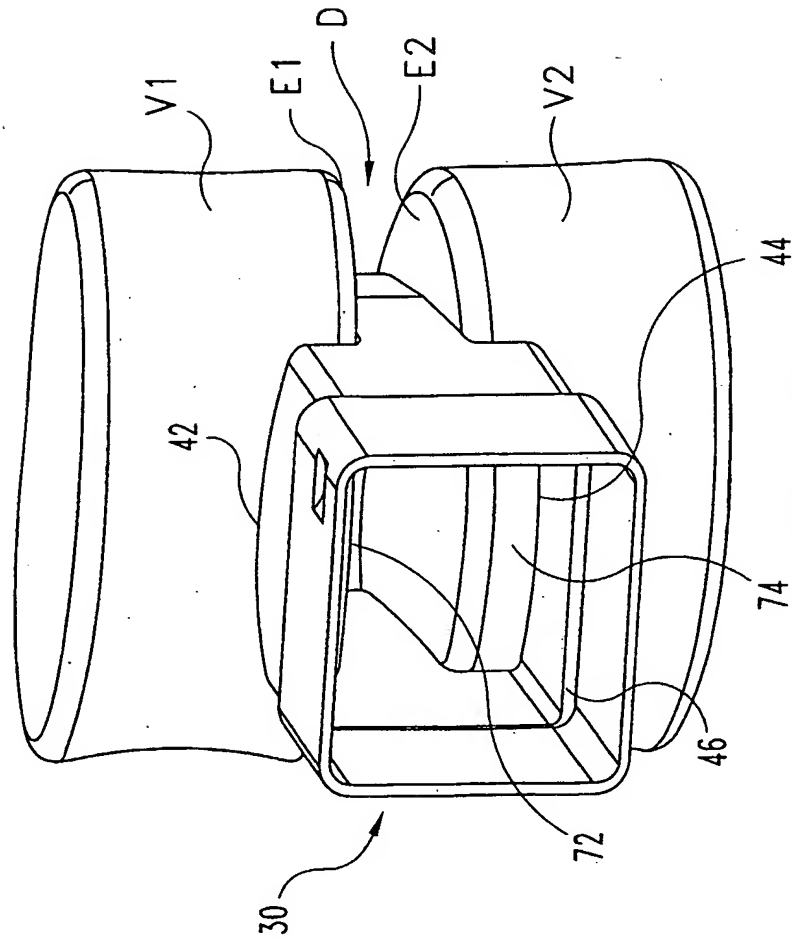


Fig. 8

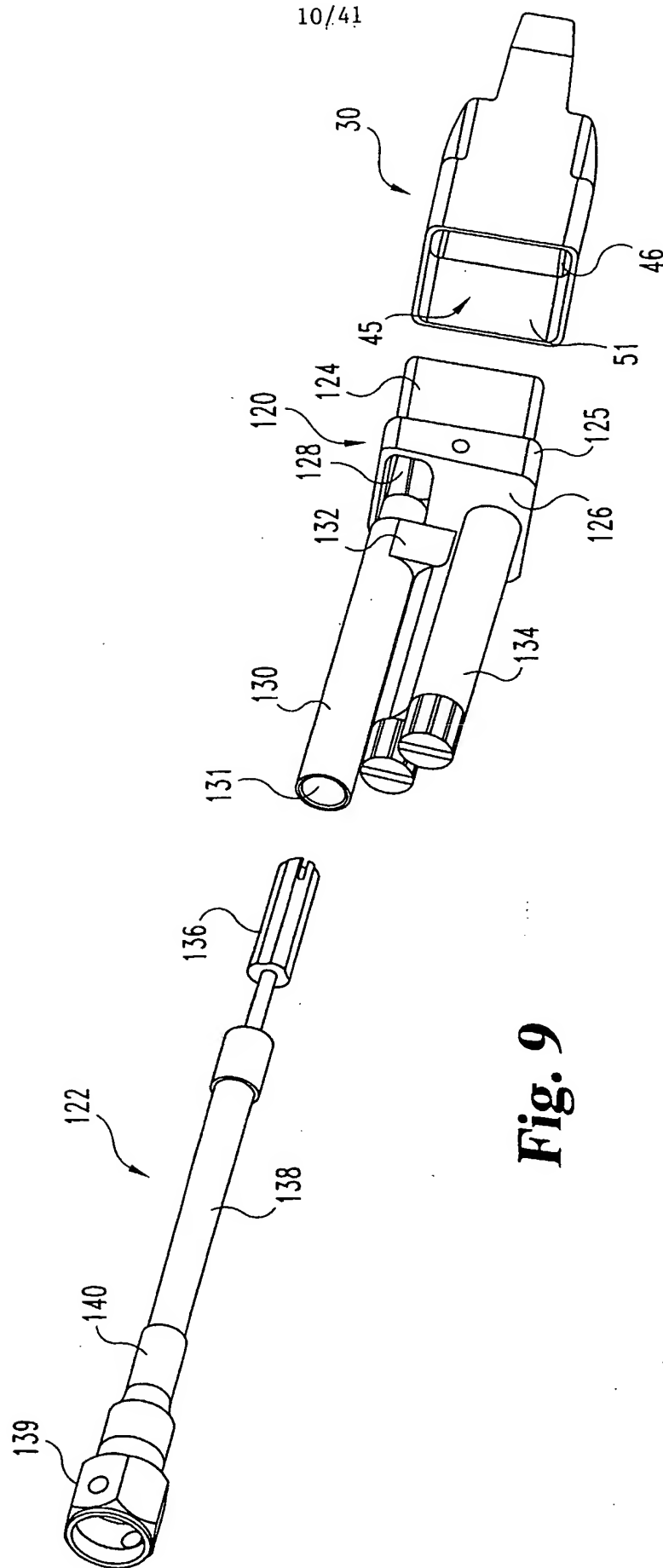


Fig. 9

11/41

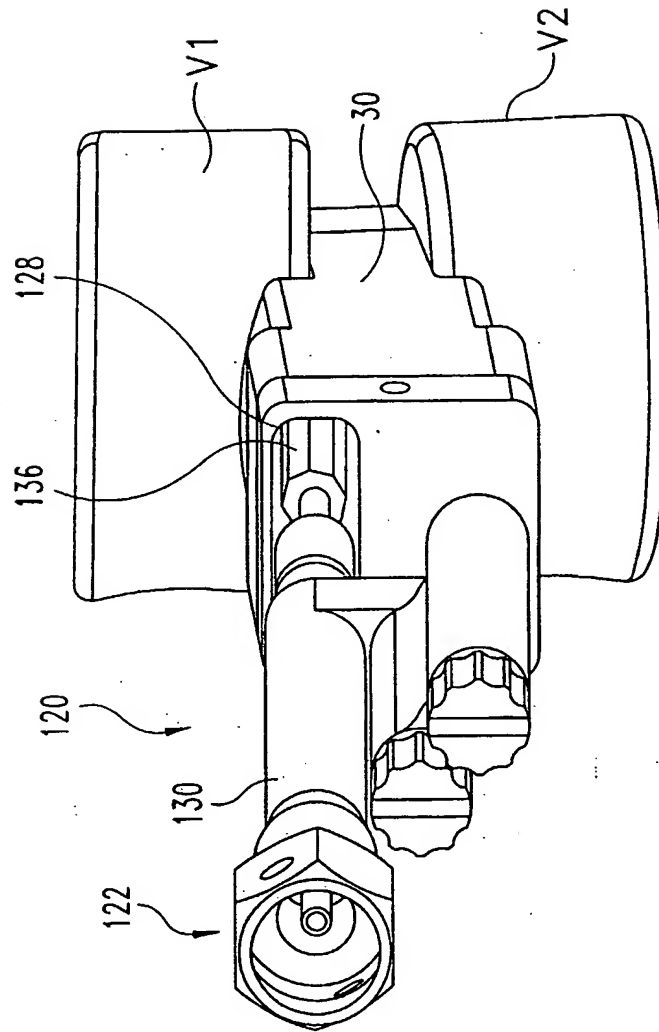
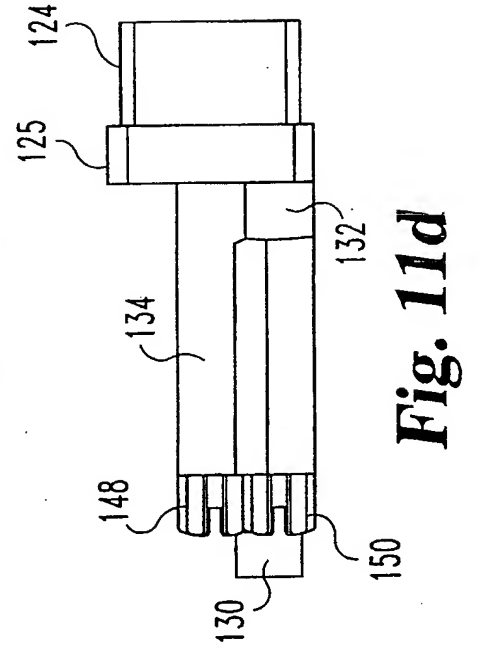
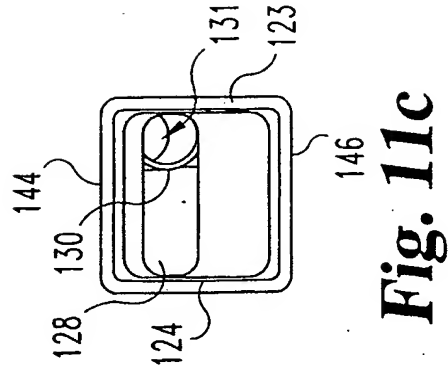
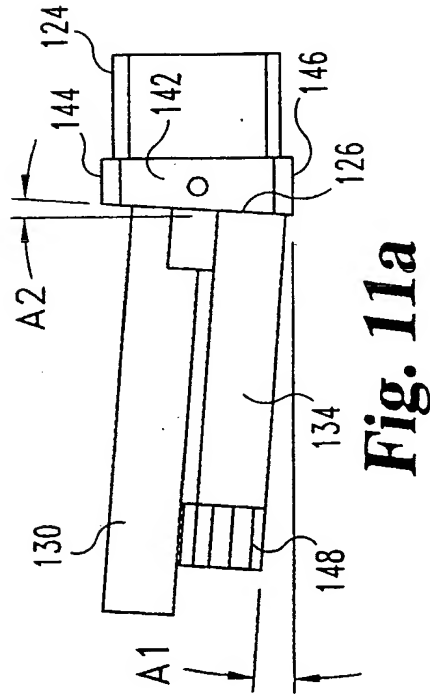
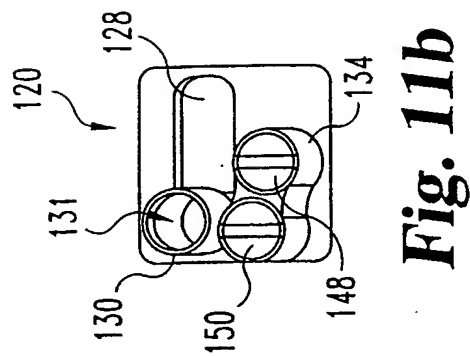
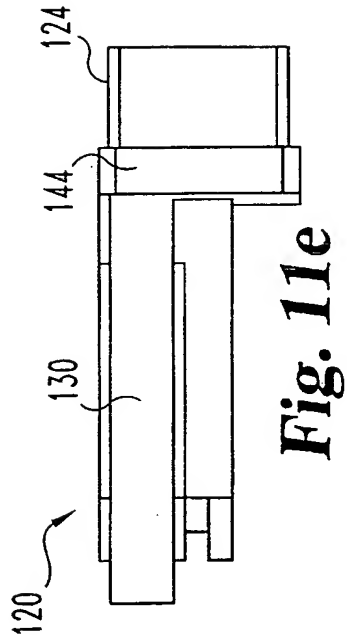


Fig. 10

12/41



13/41

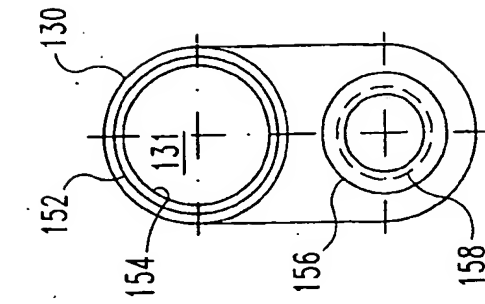


Fig. 12b

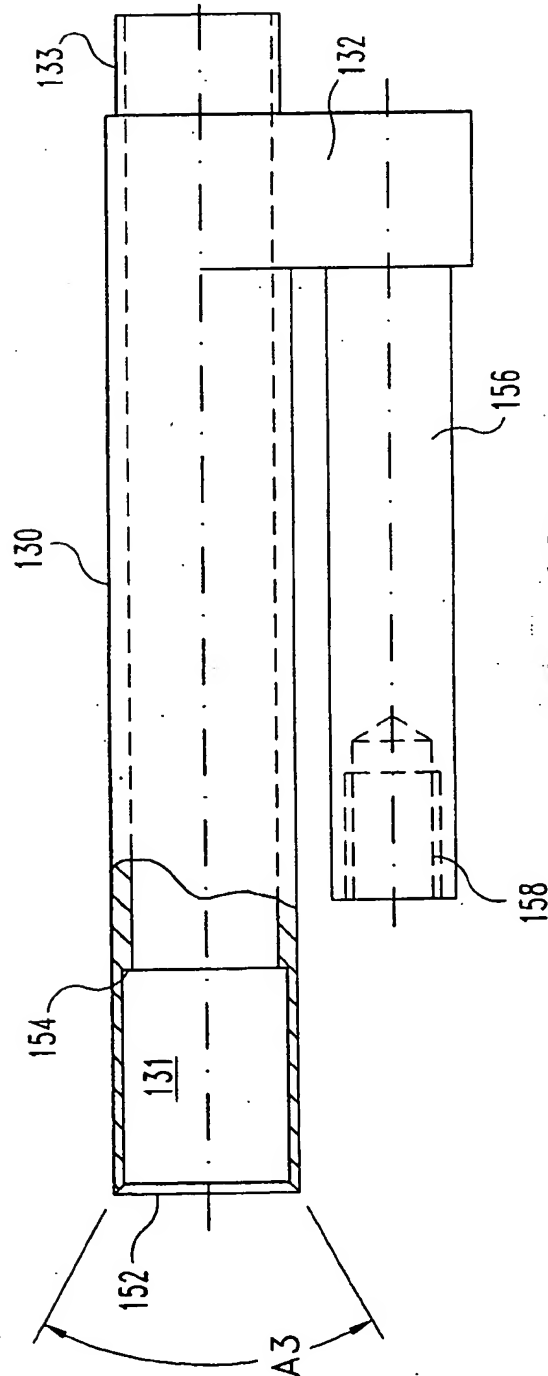


Fig. 12a

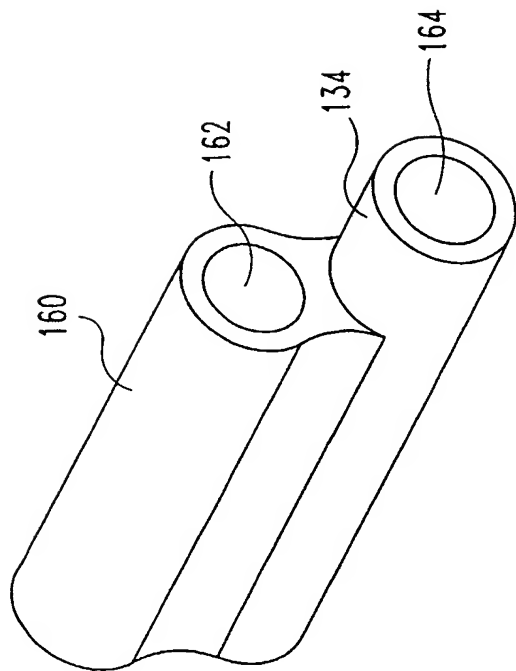


Fig. 13a

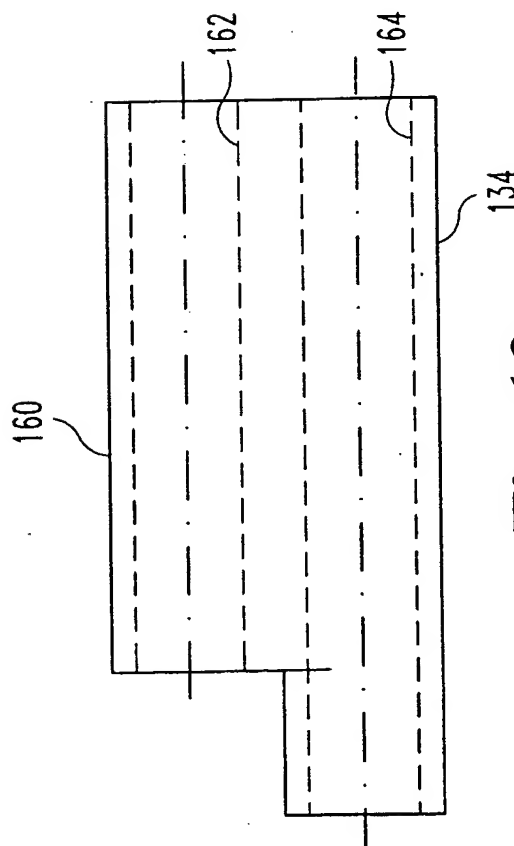


Fig. 13c

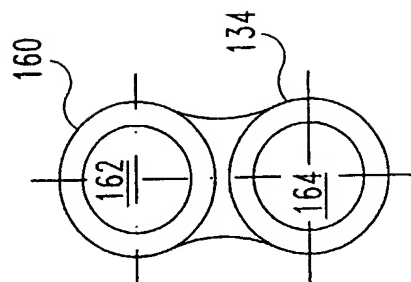
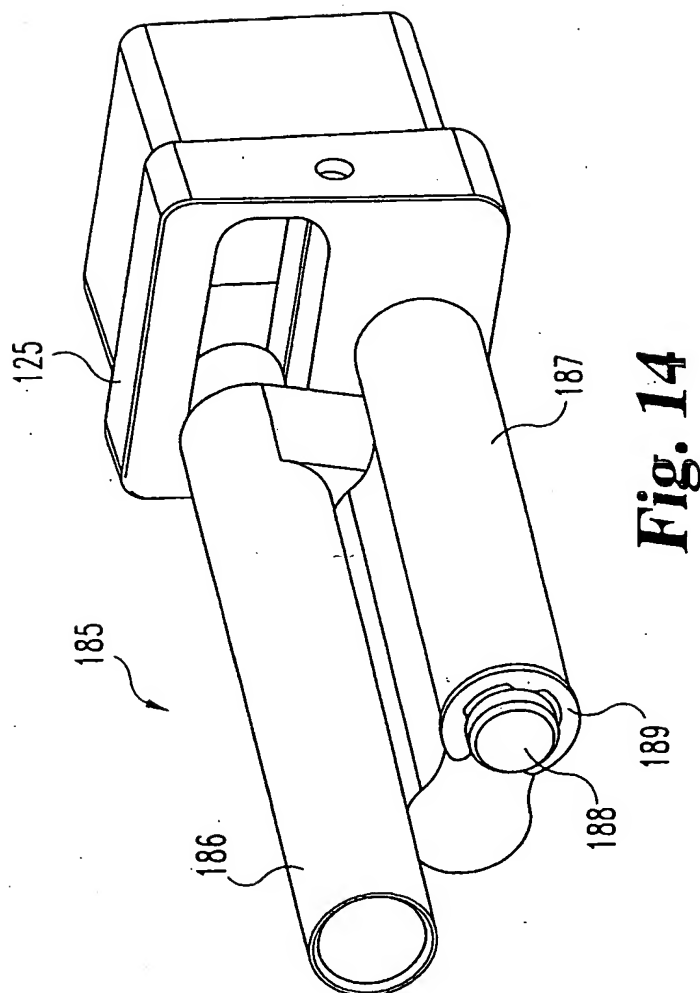


Fig. 13b



16/41

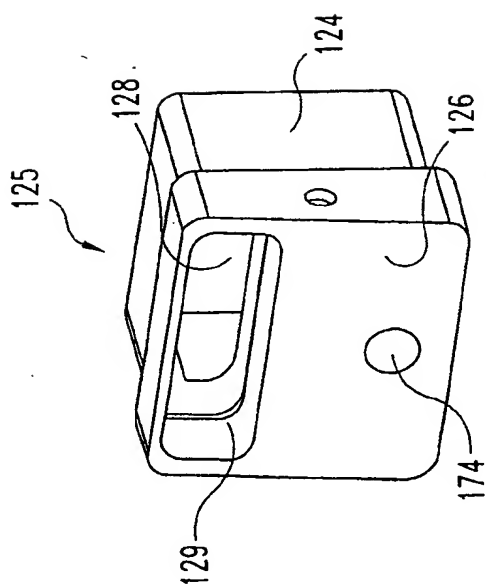


Fig. 15a

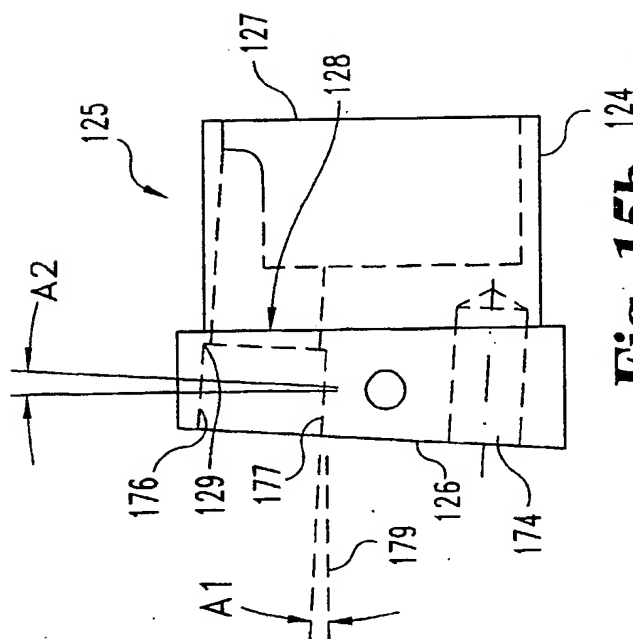


Fig. 15b

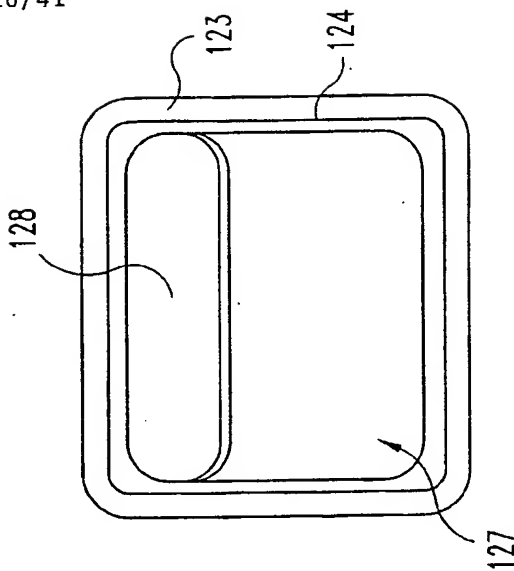


Fig. 15c

17/41

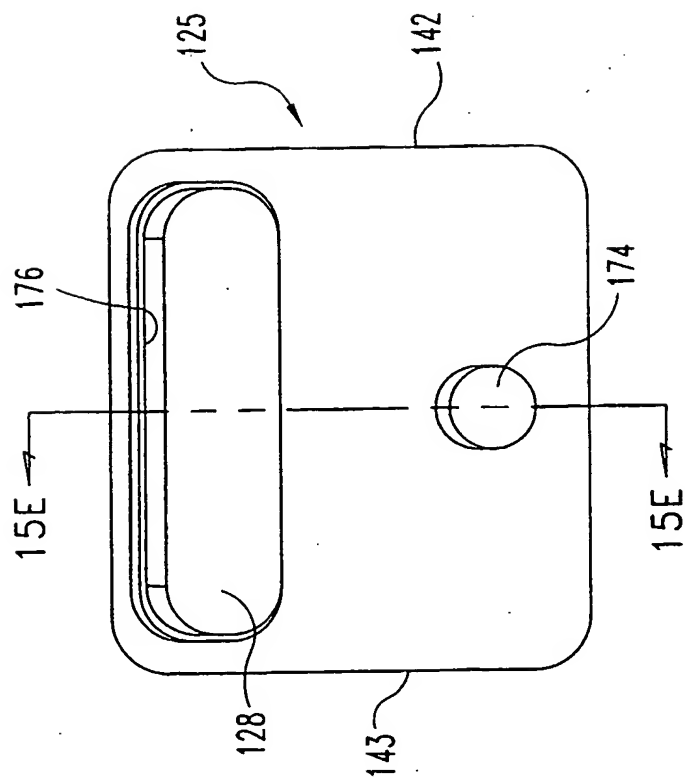


Fig. 15d

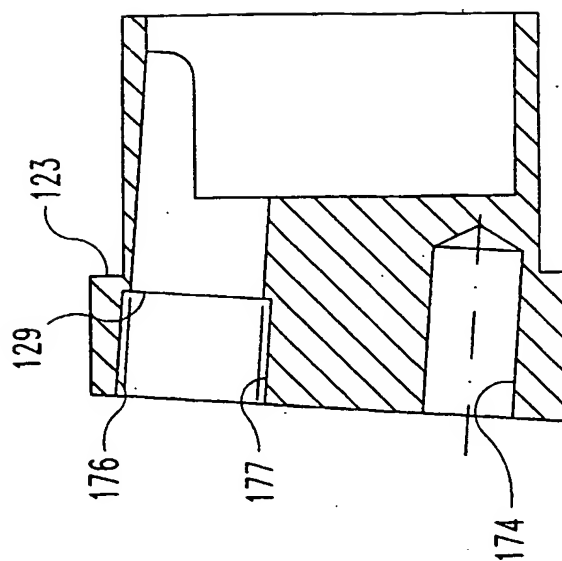


Fig. 15e

18/41

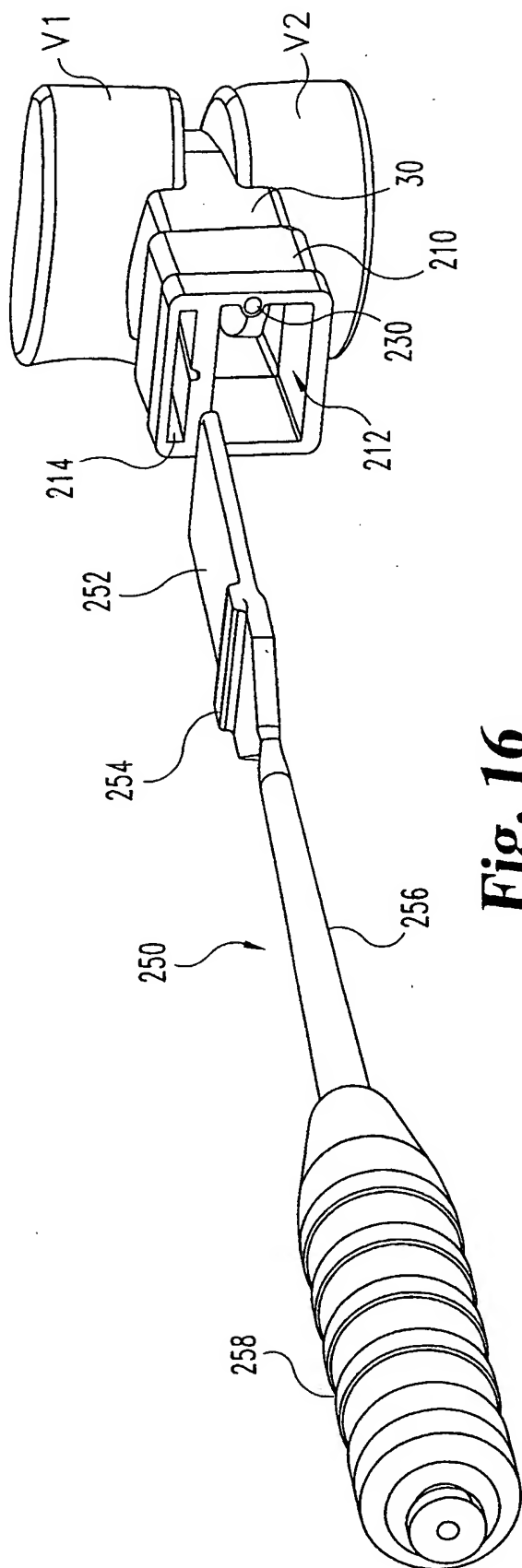


Fig. 16

19/41

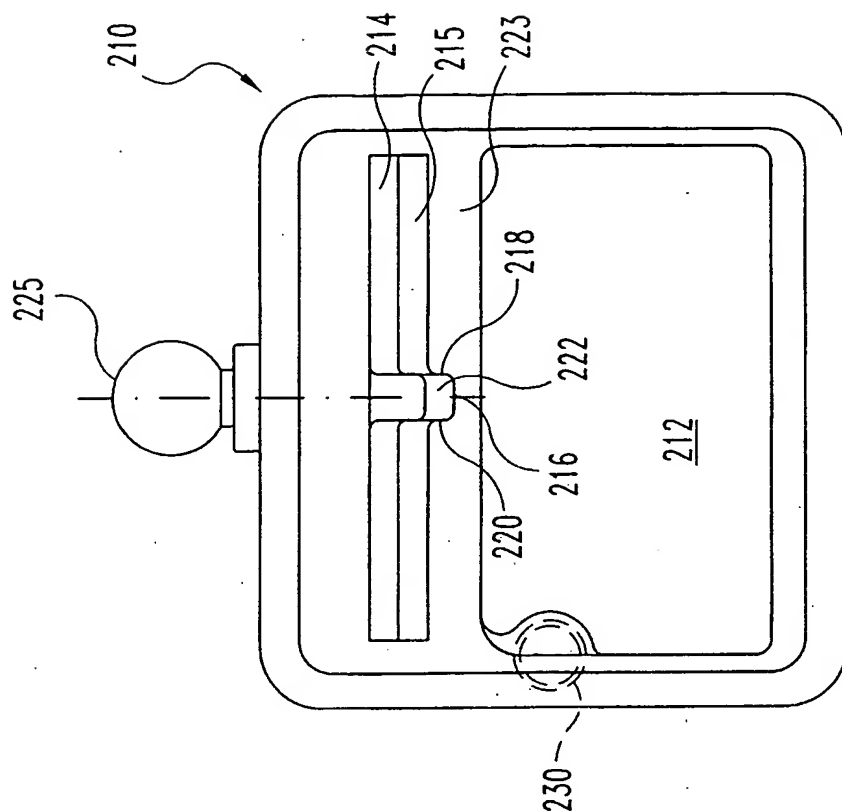


Fig. 17b

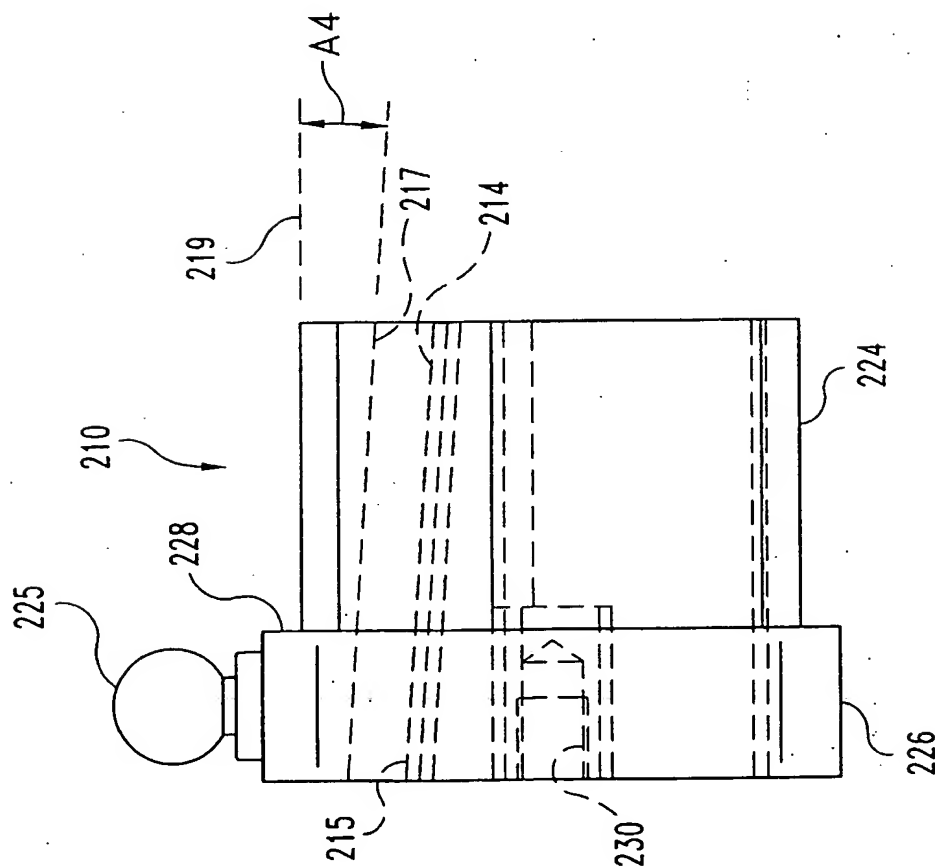
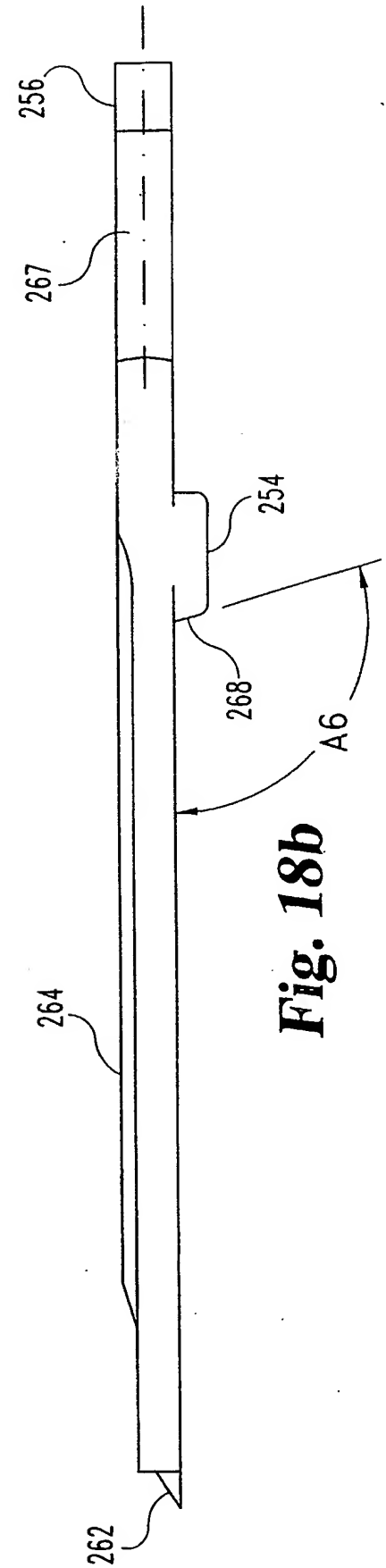
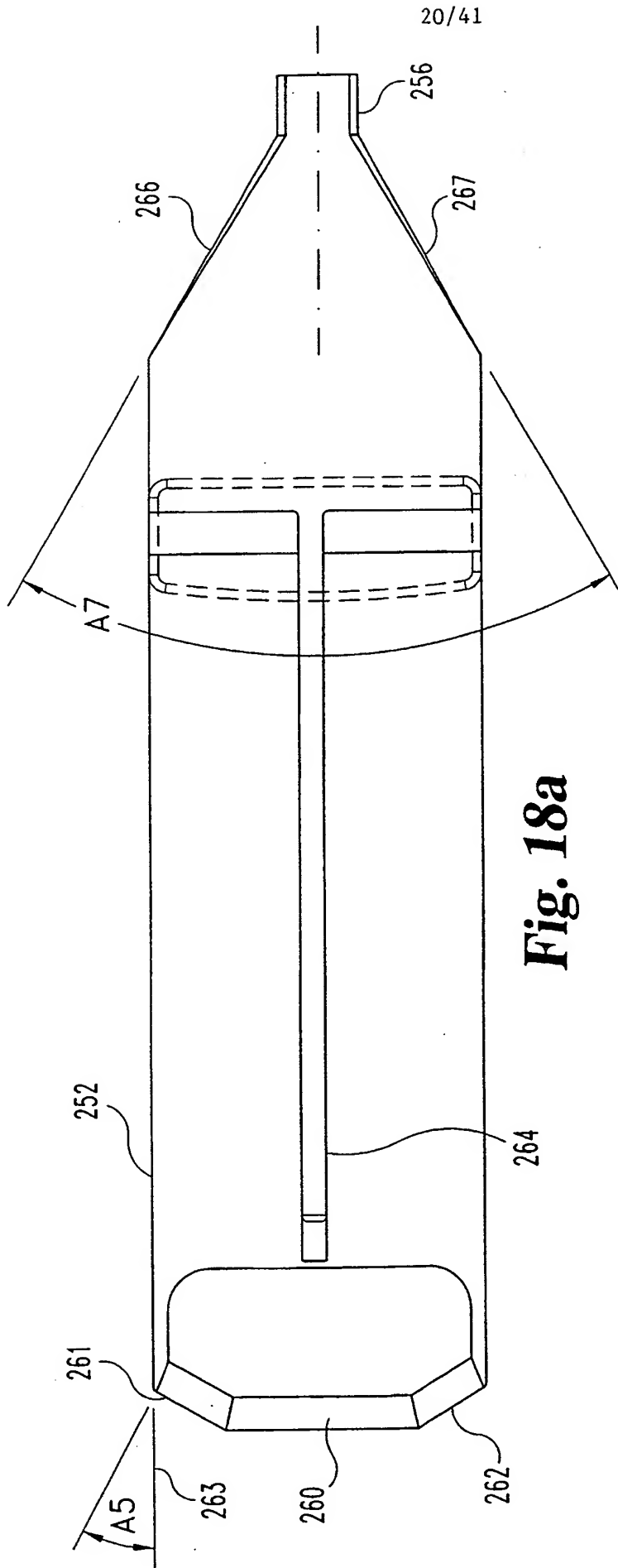


Fig. 17a



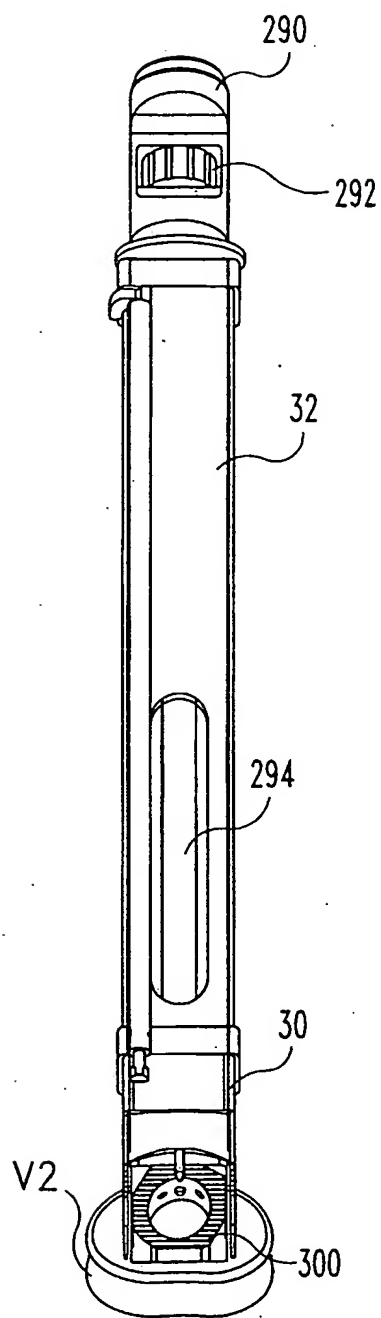


Fig. 19a

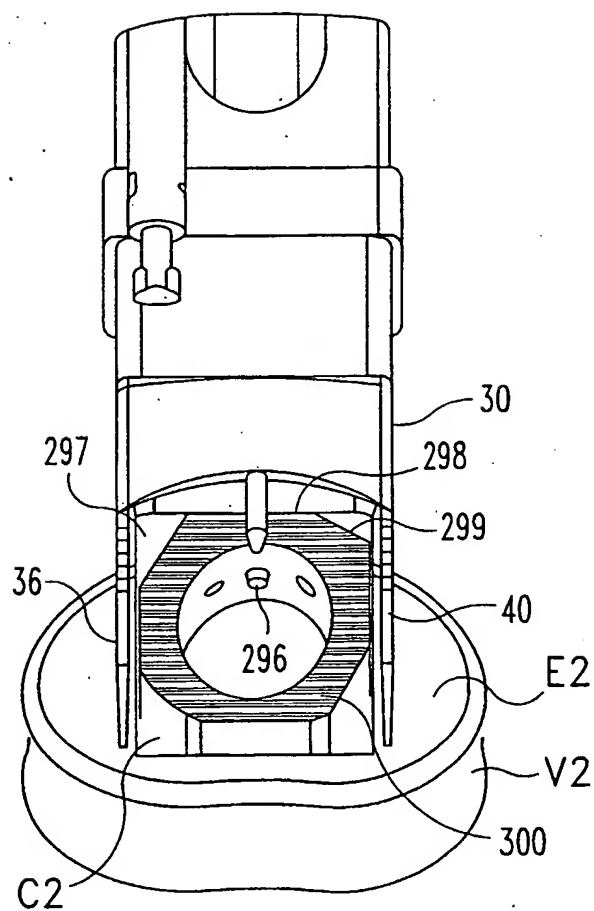


Fig. 19b

22/41

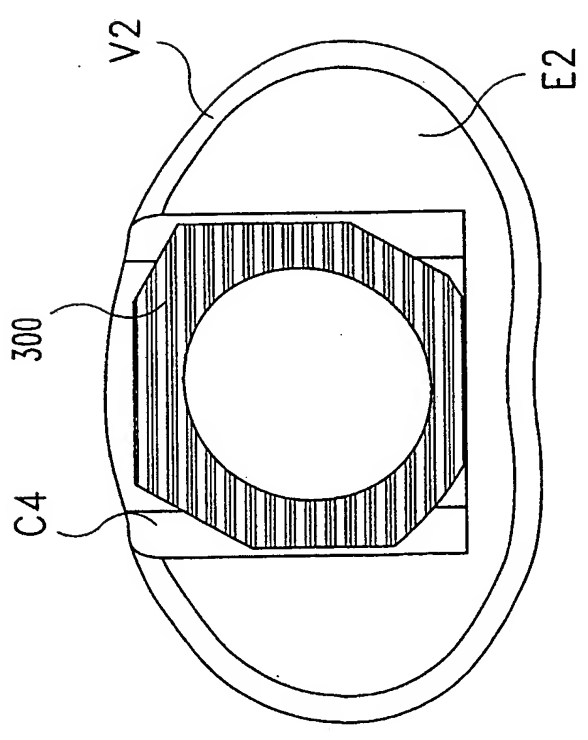


Fig. 20a

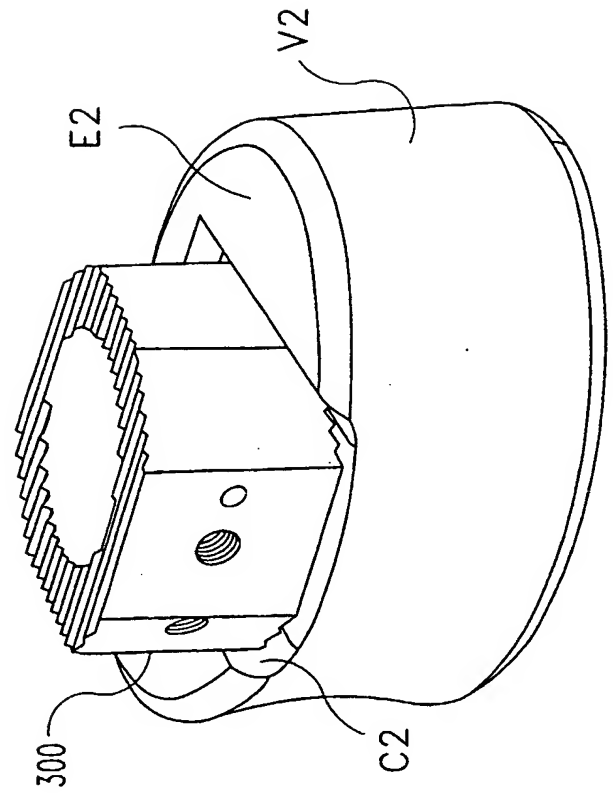
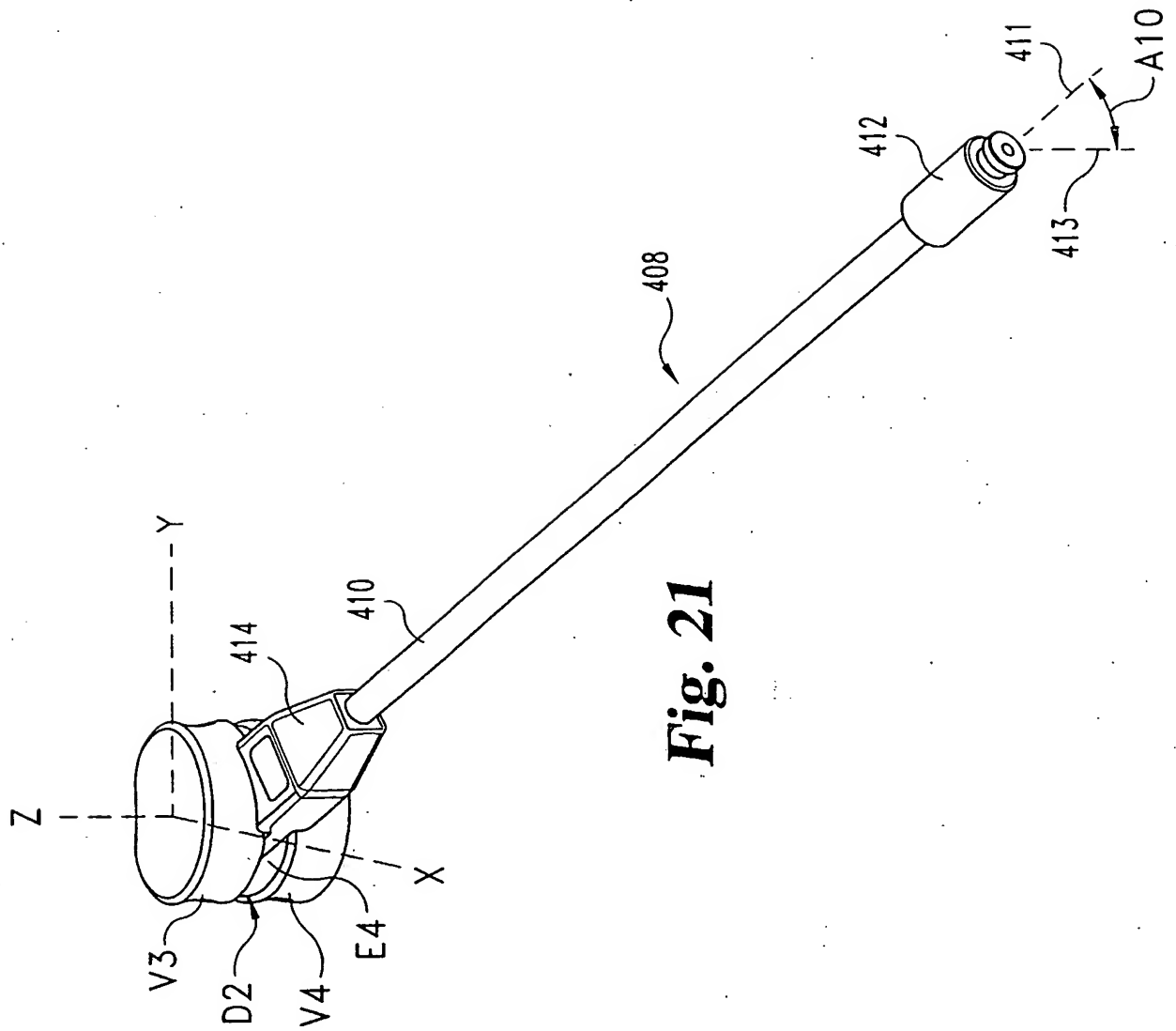
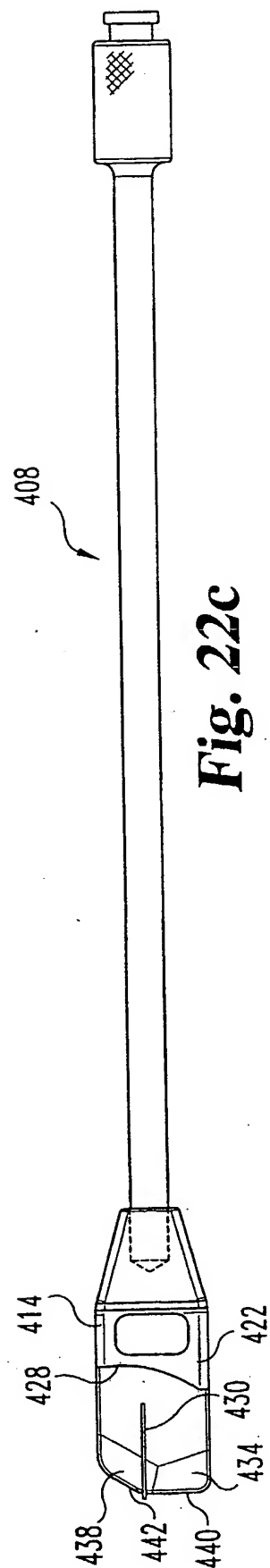
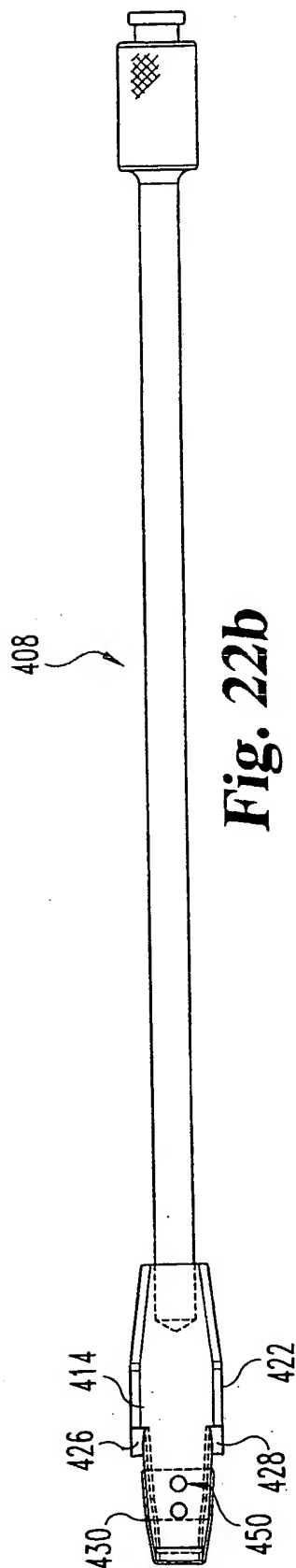
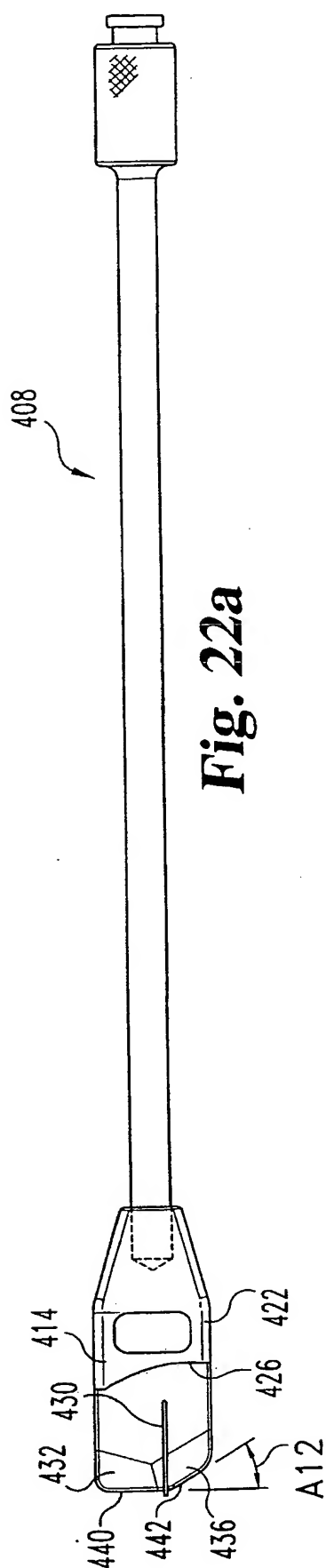


Fig. 20b





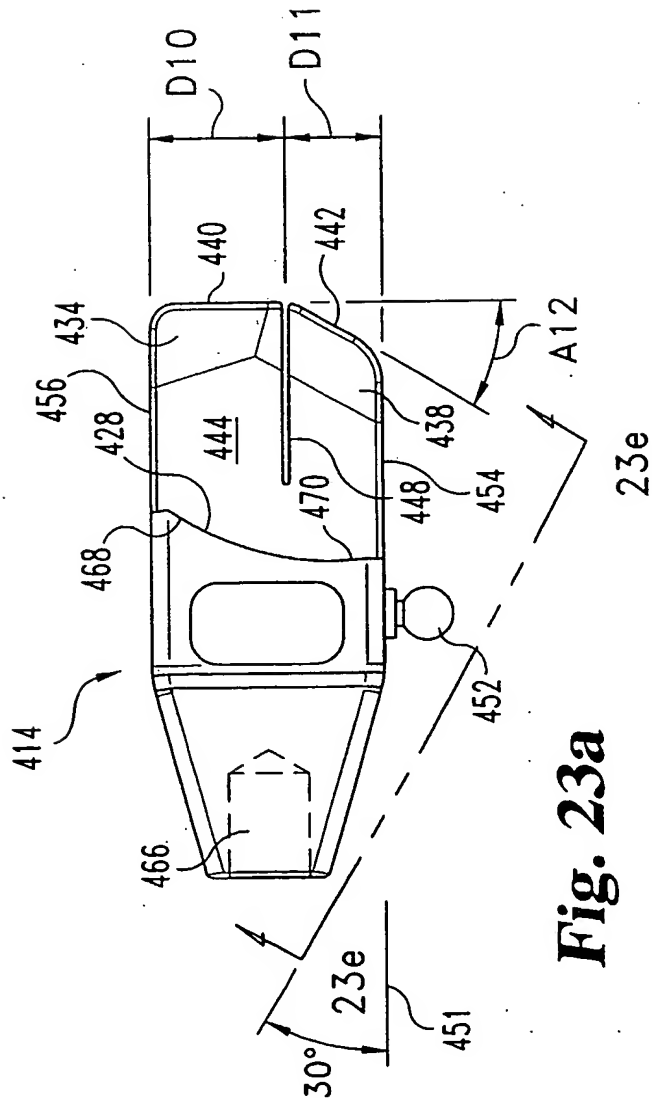


Fig. 23a

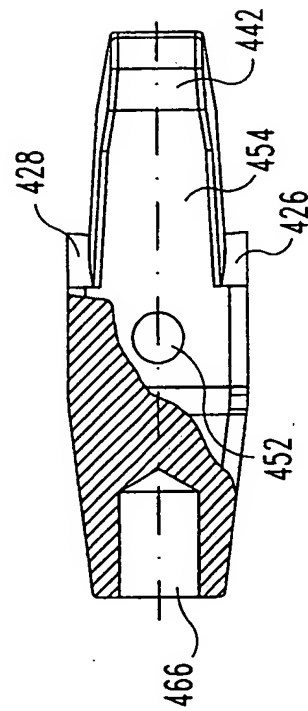


Fig. 23b

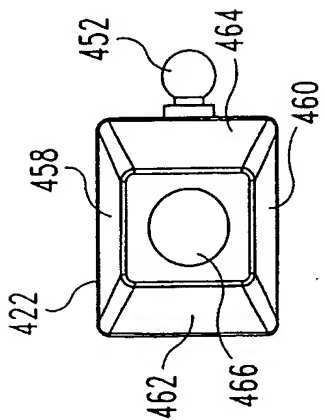


Fig. 23d

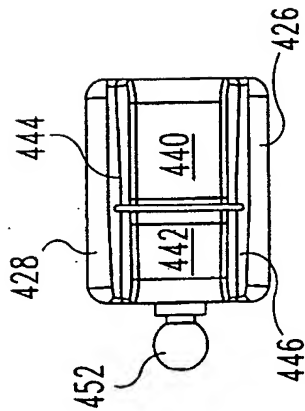


Fig. 23c

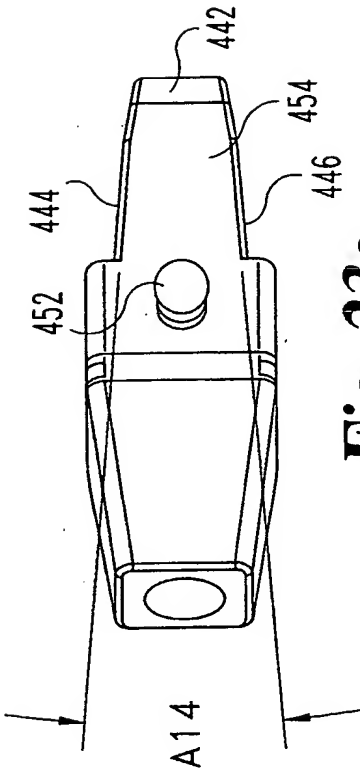


Fig. 23e

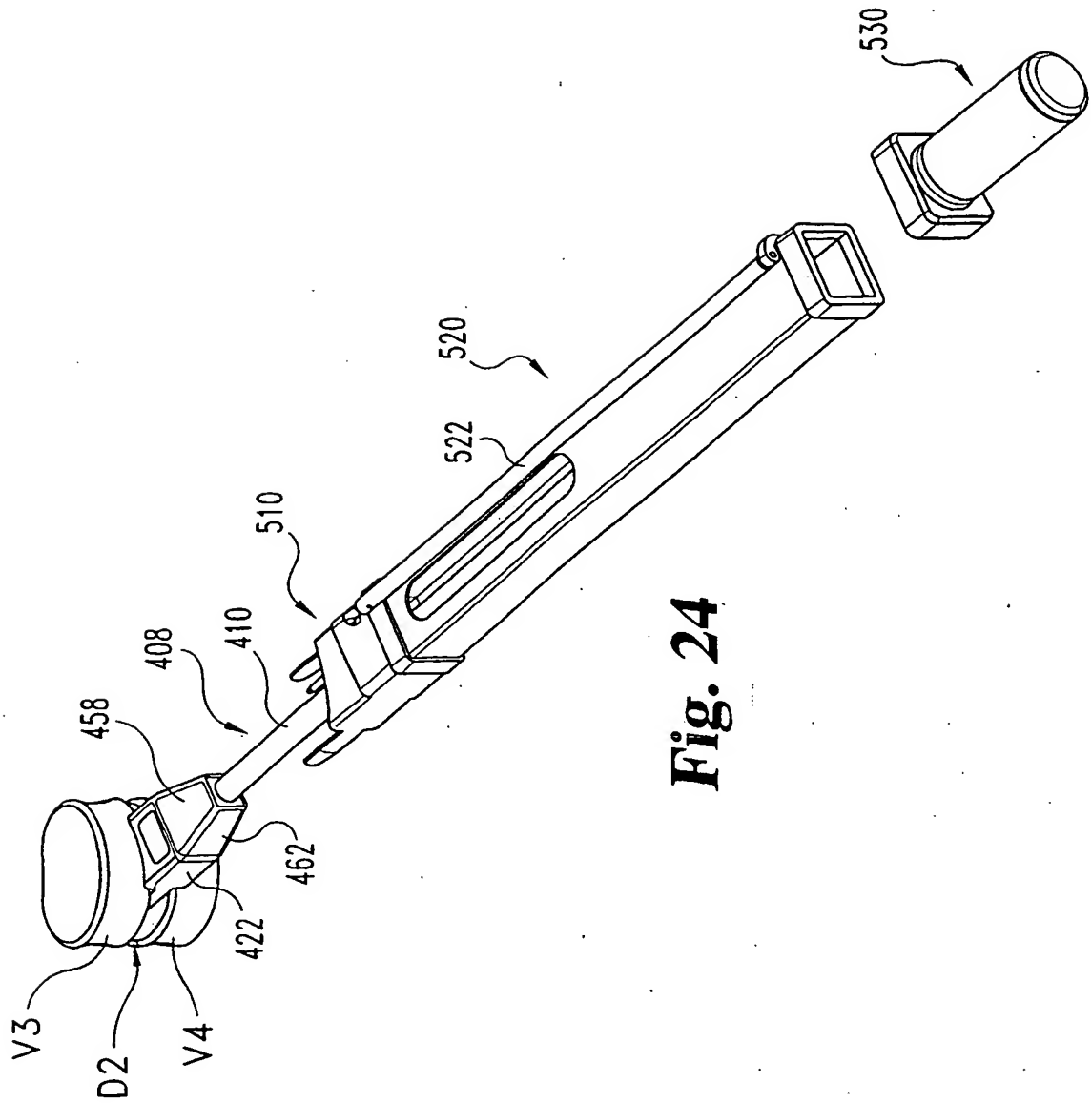


Fig. 24

28/41

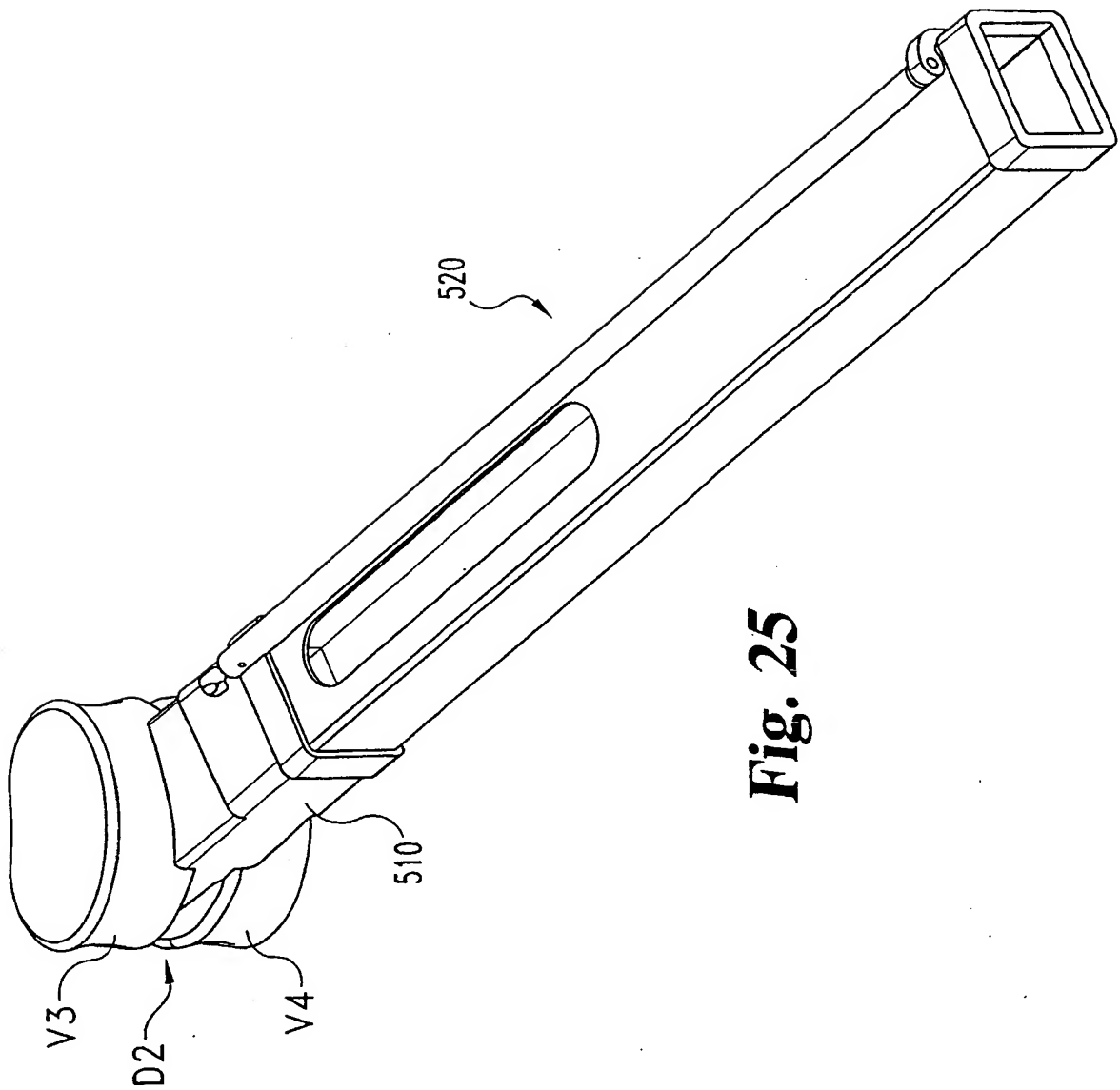


Fig. 25

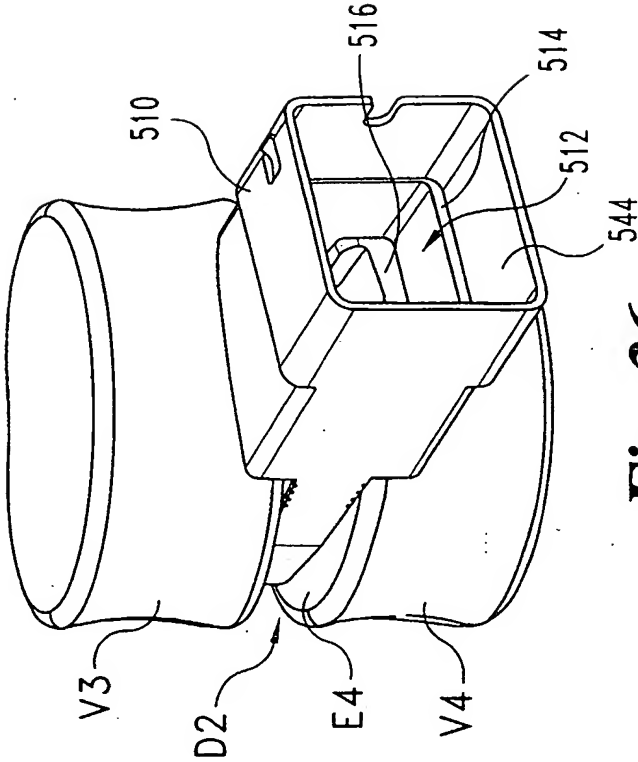


Fig. 26

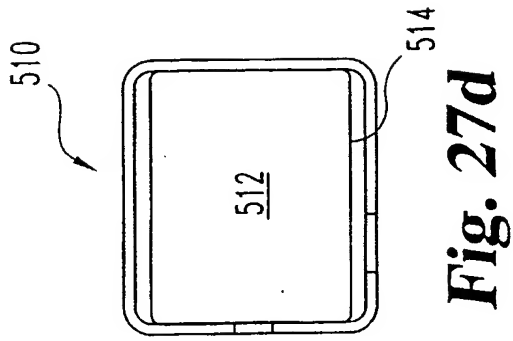


Fig. 27d

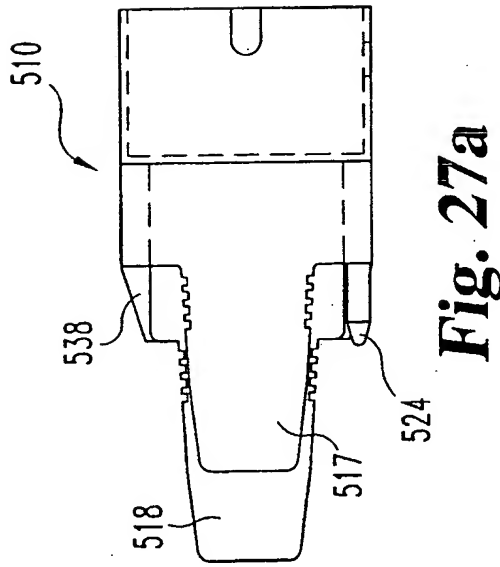


Fig. 27a

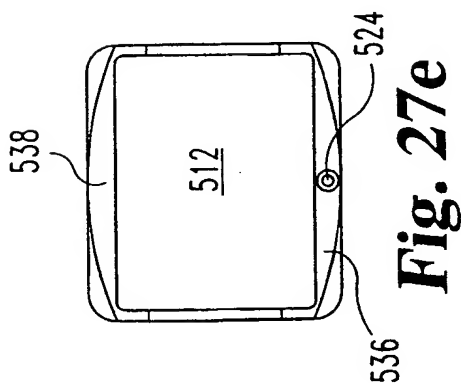


Fig. 27e

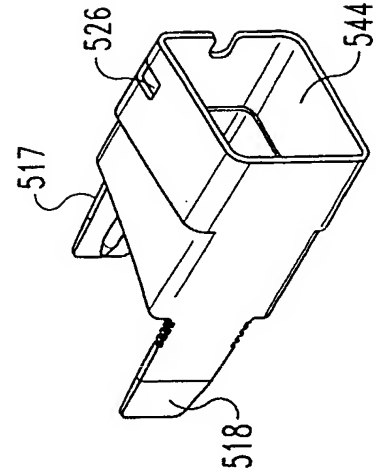


Fig. 27c

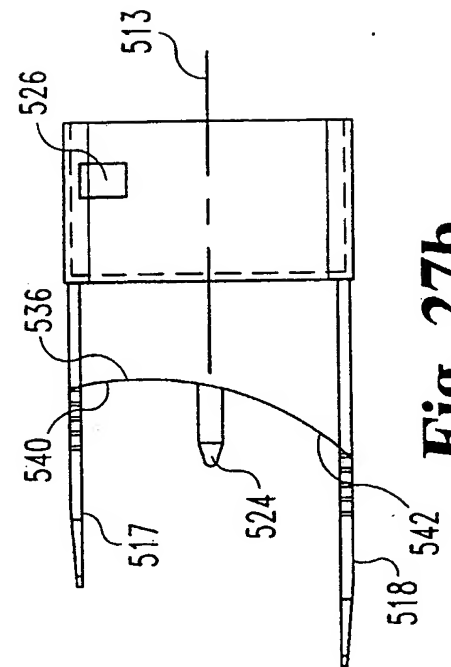


Fig. 27b

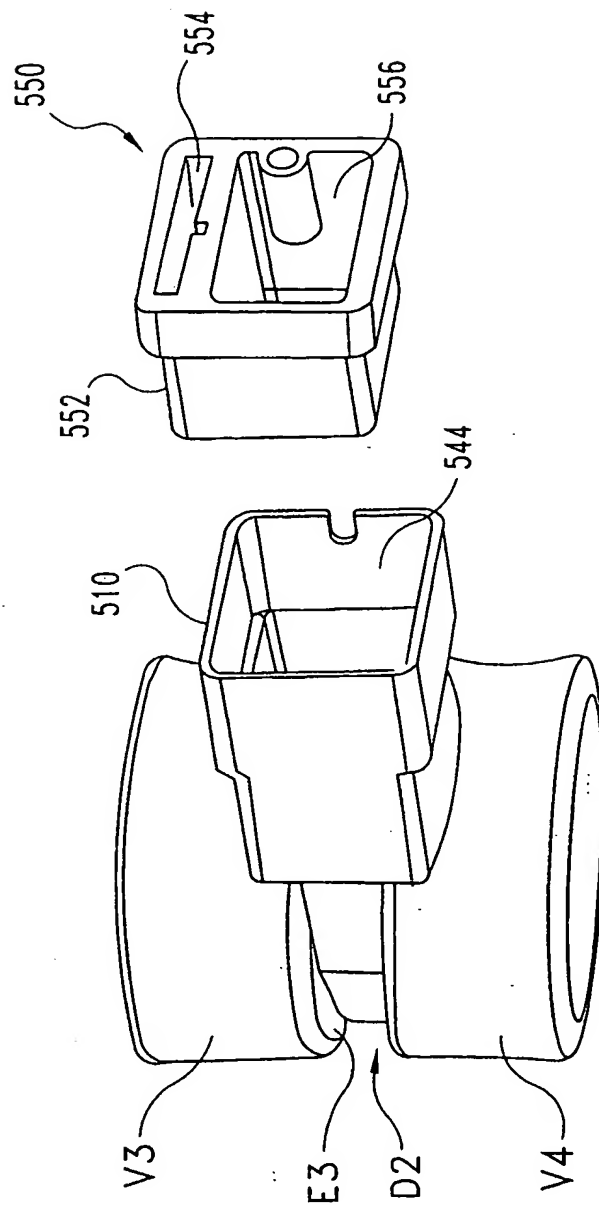
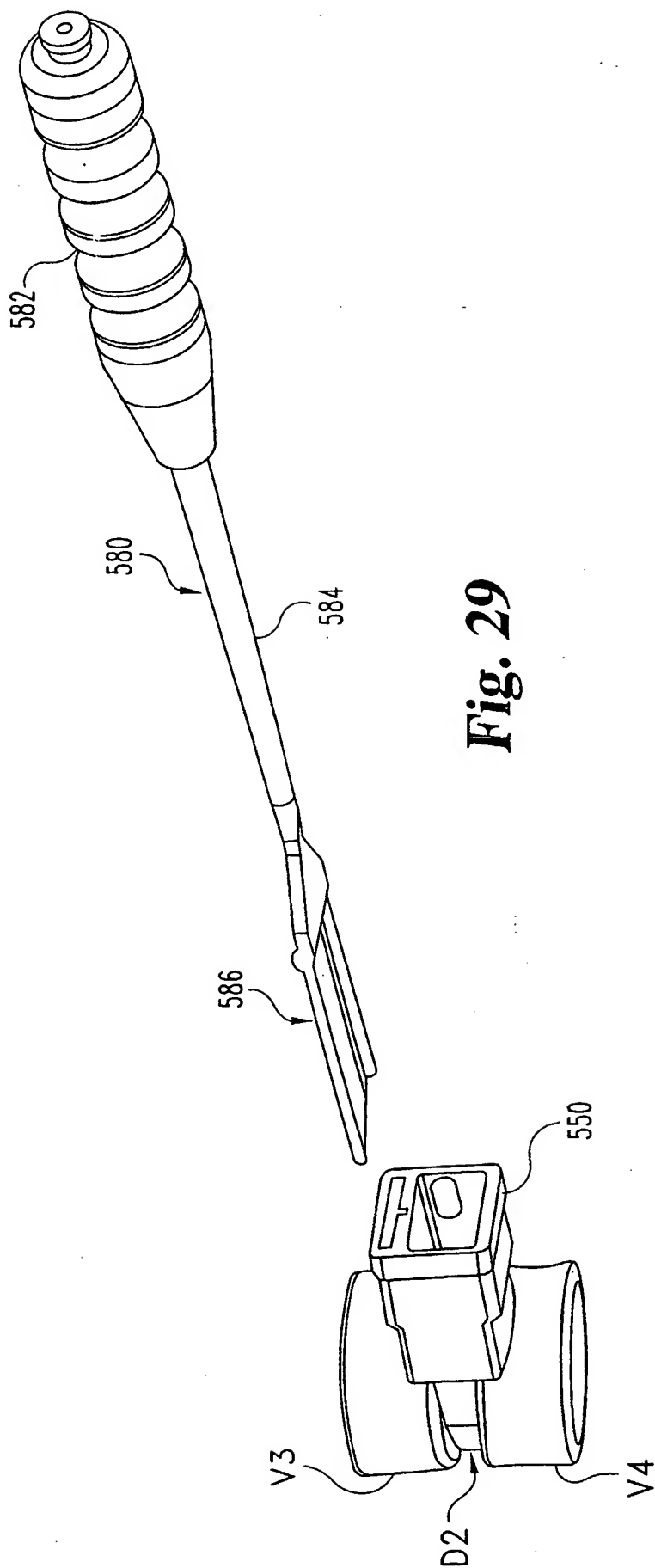


Fig. 28



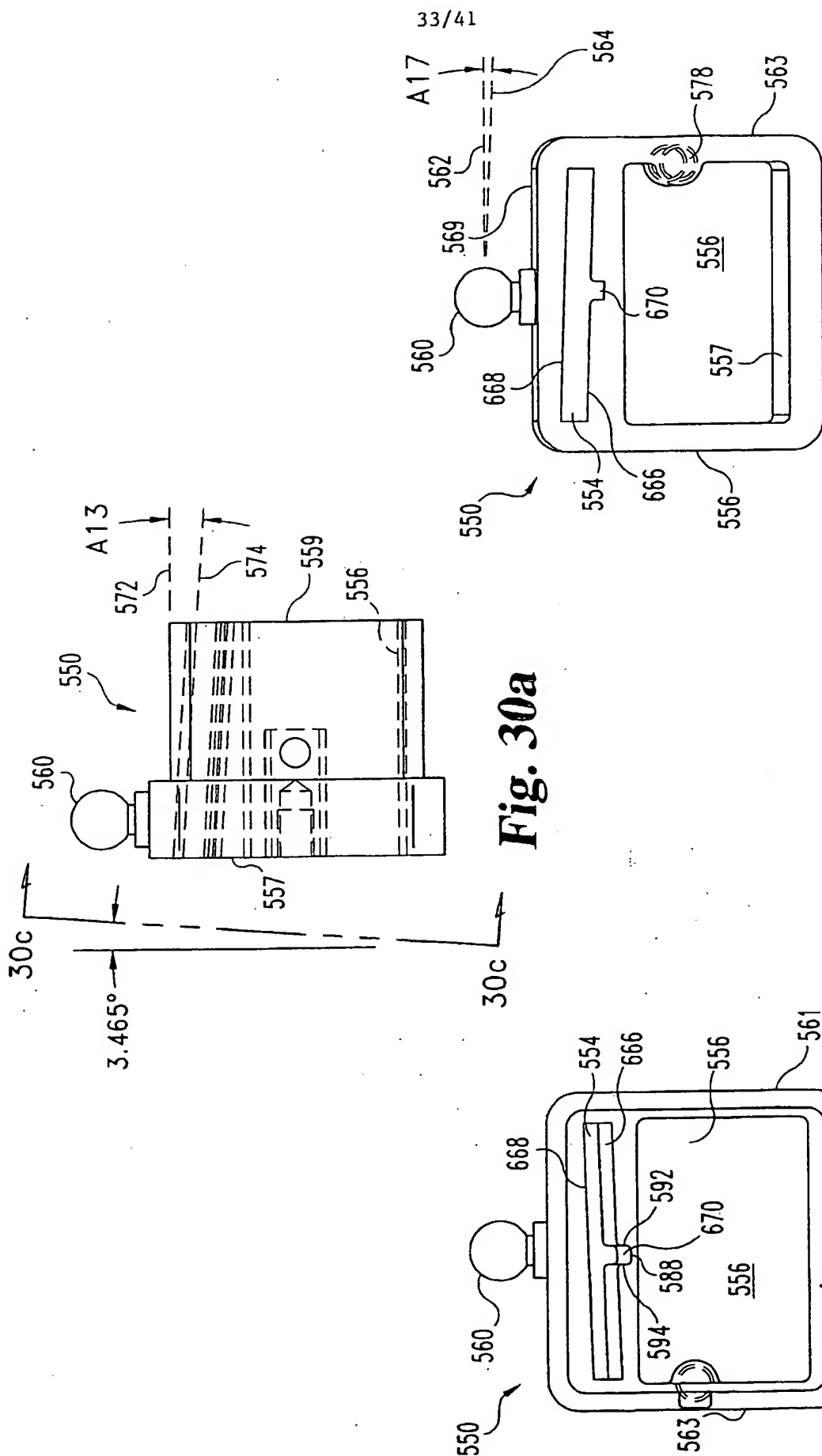
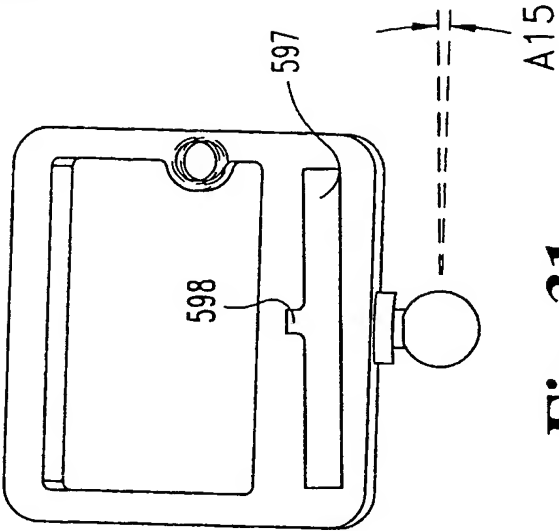
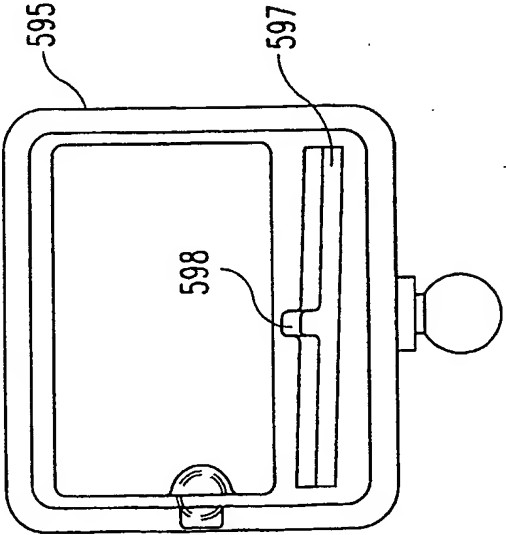
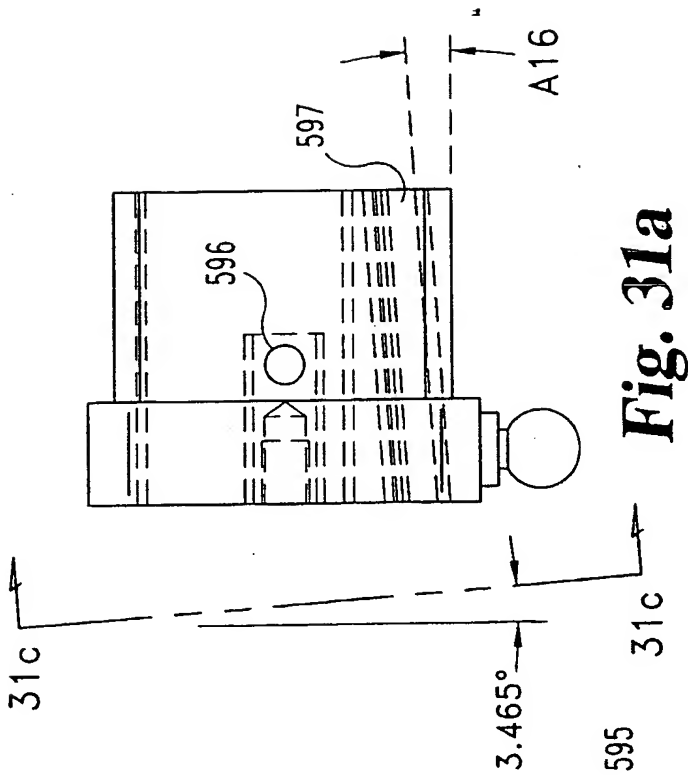
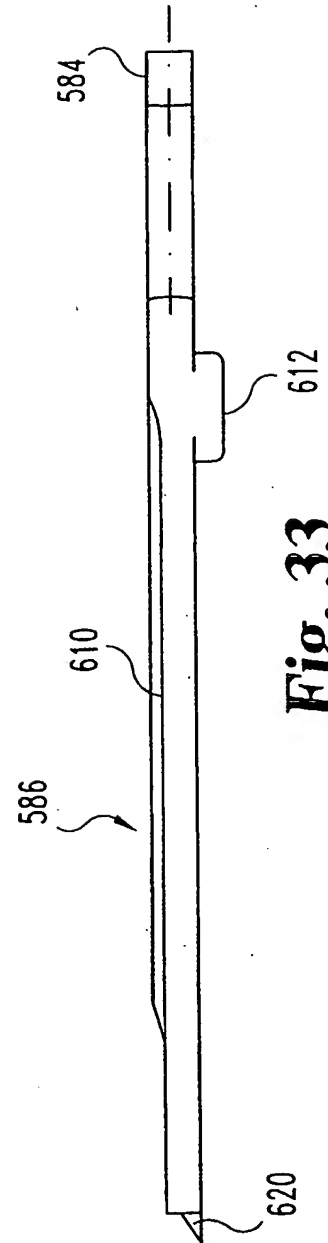
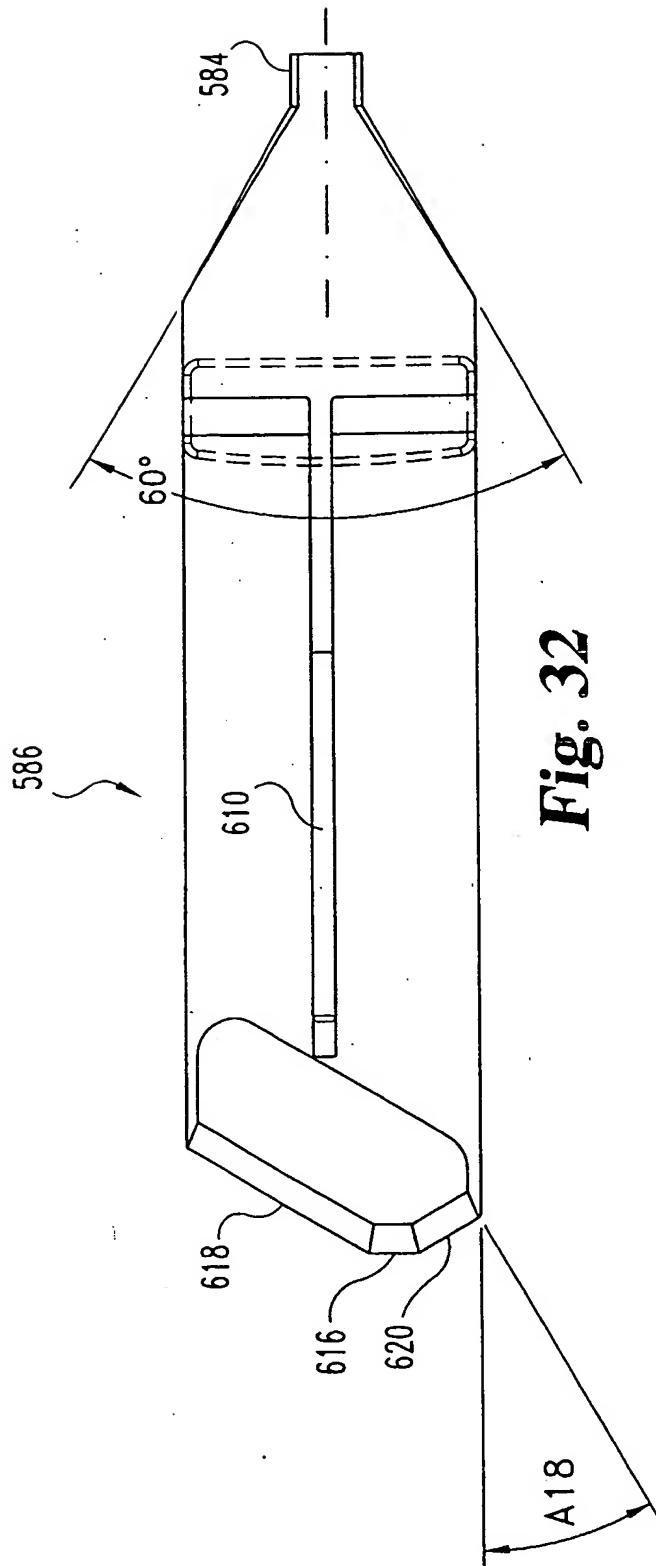


Fig. 30a

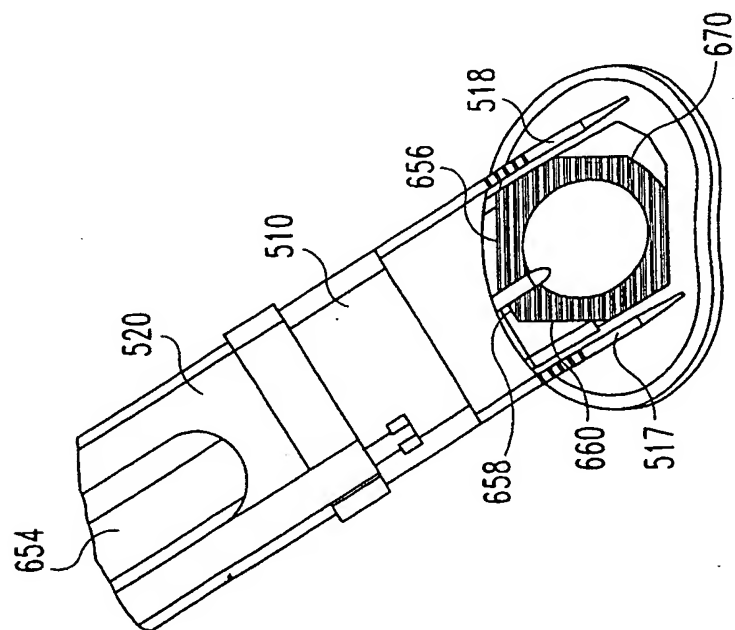
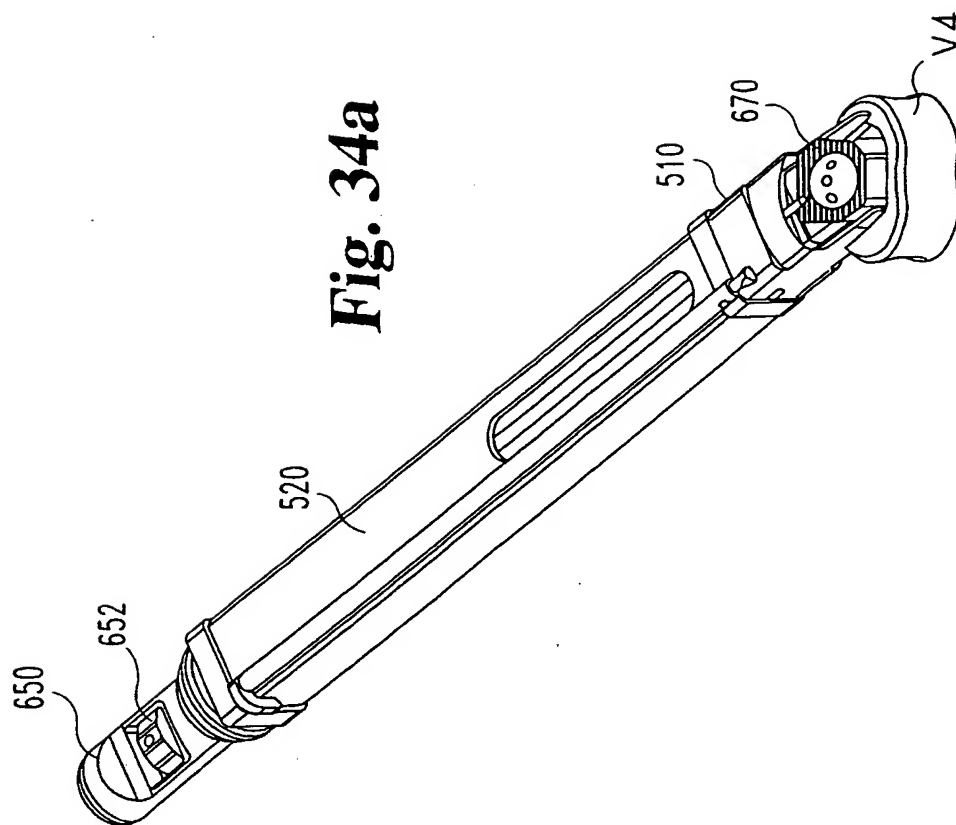
Fig. 30c

Fig. 30b





36/41



37 / 41

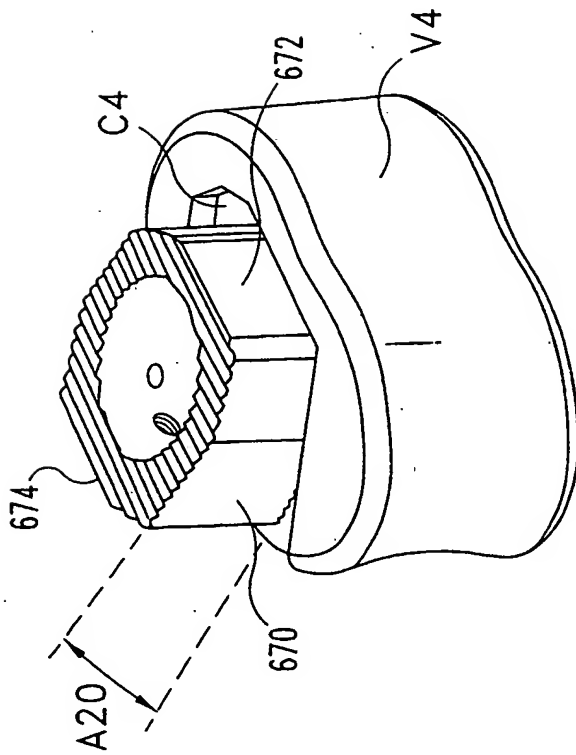


Fig. 35

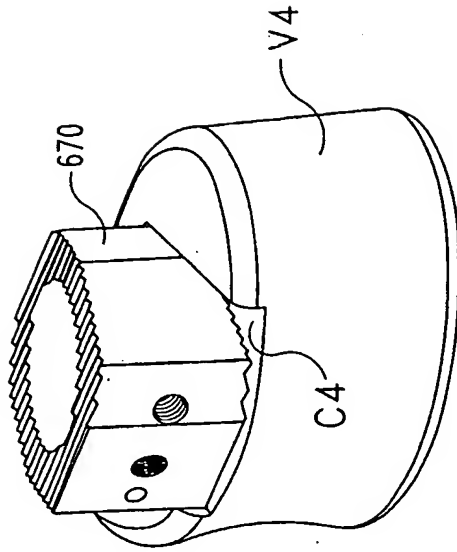


Fig. 36

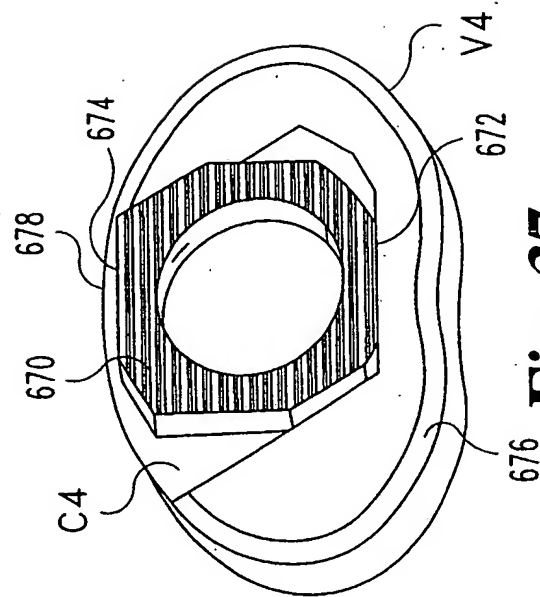


Fig. 37

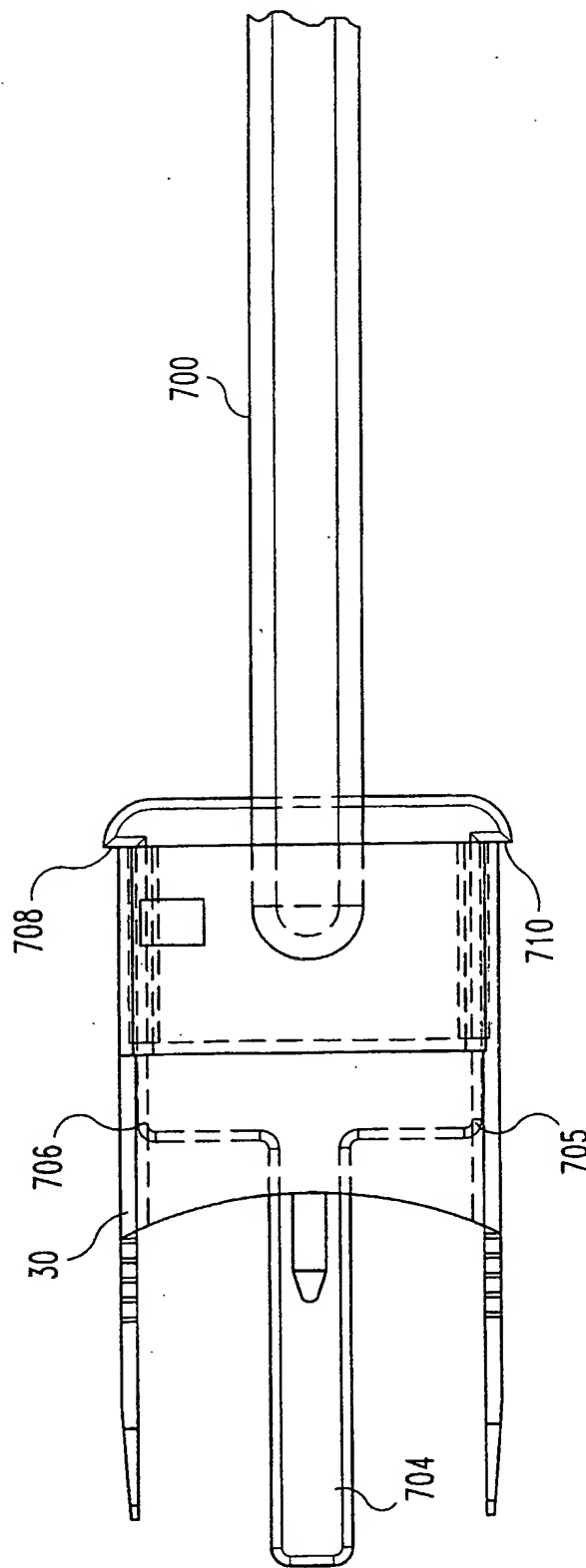


Fig. 38

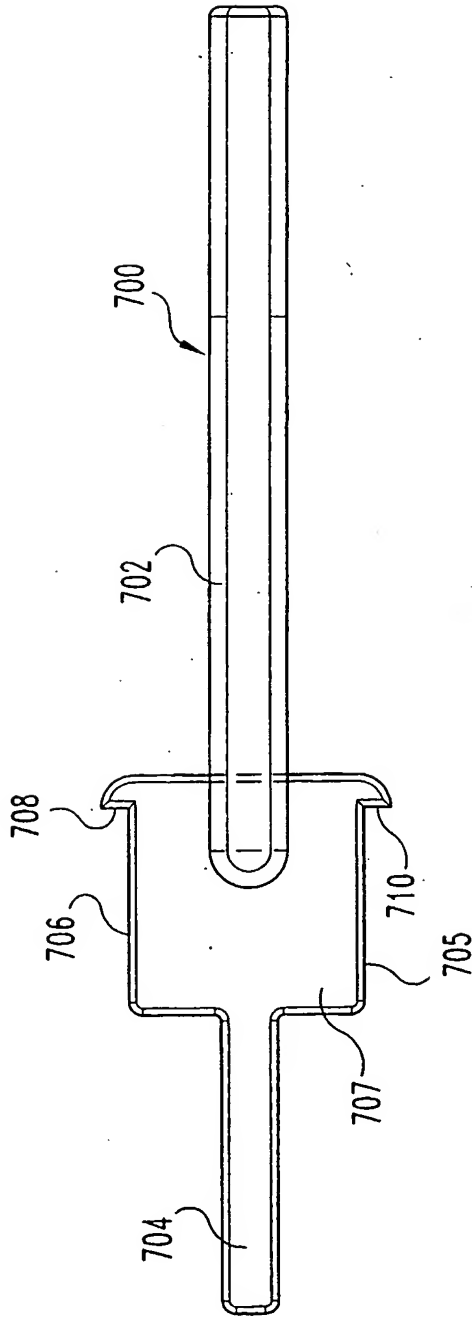


Fig. 39a

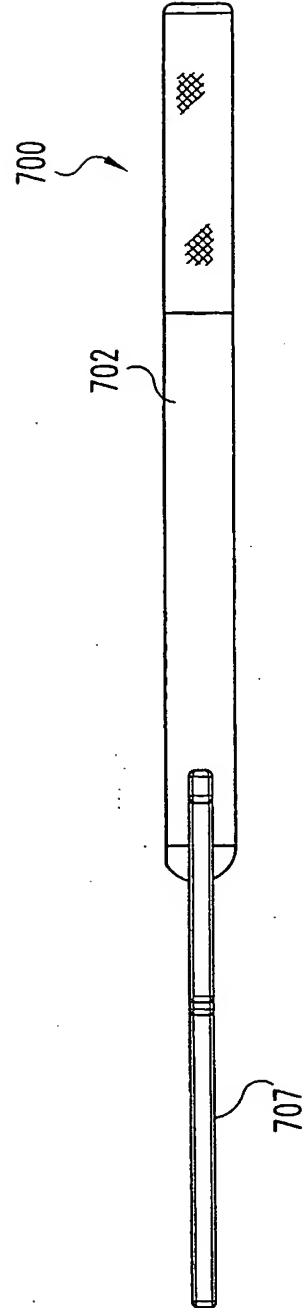


Fig. 39b

40/41

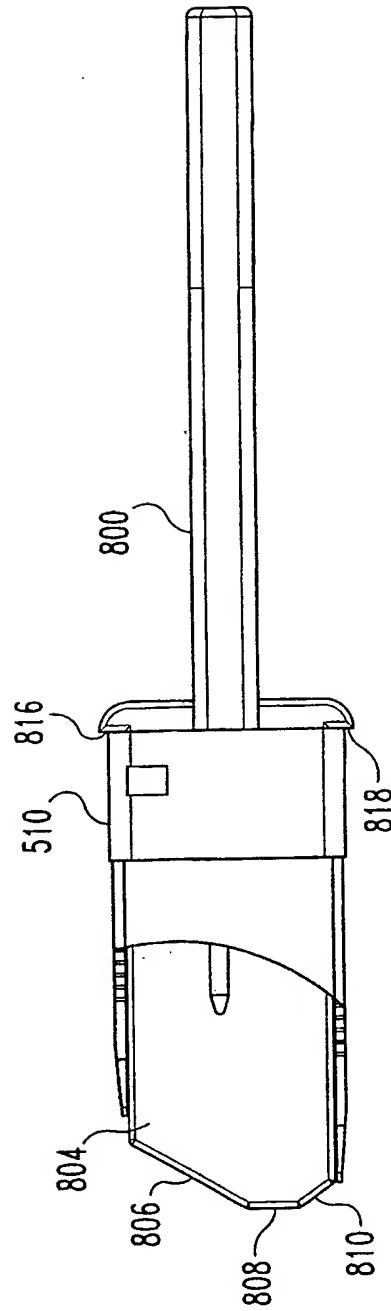


Fig. 40

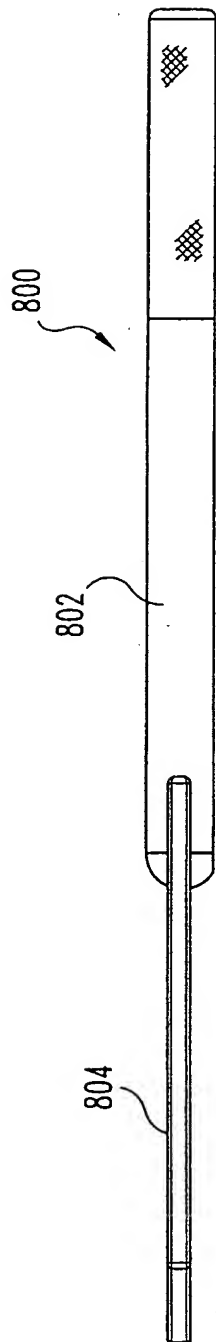


Fig. 41b

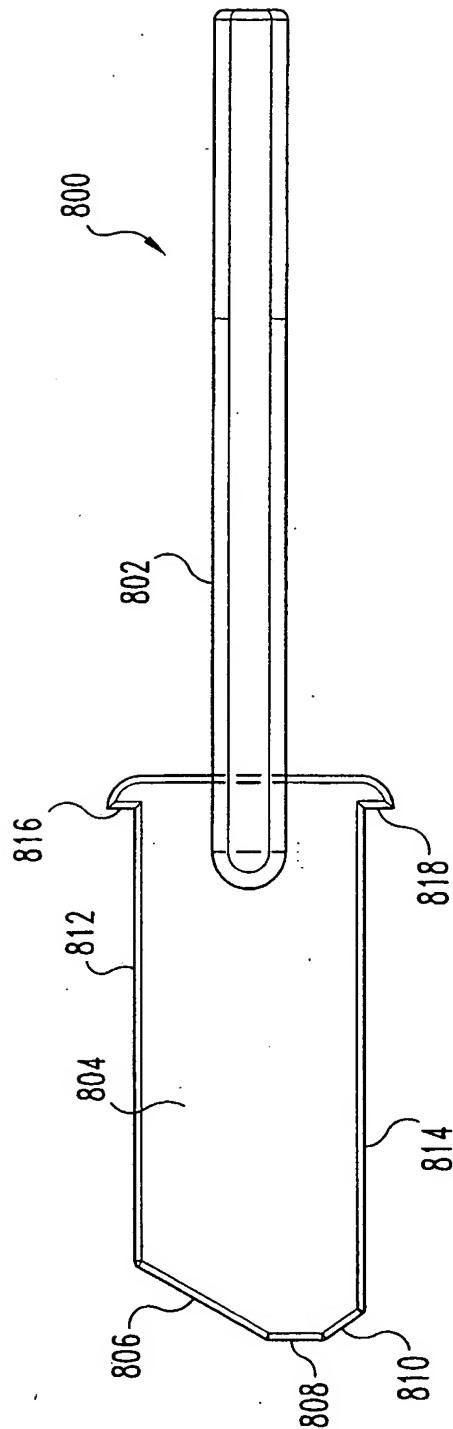


Fig. 41a

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
30 August 2001 (30.08.2001)

PCT

(10) International Publication Number
WO 01/62166 A3

(51) International Patent Classification⁷: A61B 17/16, 17/17, 17/02

(21) International Application Number: PCT/US01/05500

(22) International Filing Date: 22 February 2001 (22.02.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/184,107 22 February 2000 (22.02.2000) US

(71) Applicant (for all designated States except US): SDGI HOLDINGS, INC. [US/US]; 300 Delaware Avenue, Suite 508, Wilmington, DE 19801 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): MCGAHAN, Thomas, V. [US/US]; 4904 Harvest Fields Circle, Memphis, TN 38125 (US). DERIDDER, Steven, D. [US/US]; 6255 Skylight Drive, Bartlett, TN 38135 (US). LANGE, Eric, C. [US/US]; 2457 Calkins Road, Germantown, TN 38139 (US).

(74) Agents: LOWES, J., Andrew et al.; Woodard, Emhardt, Naughton, Moriarty & McNett, Bank One Center/Tower, Suite 3700, 111 Monument Circle, Indianapolis, IN 46204 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

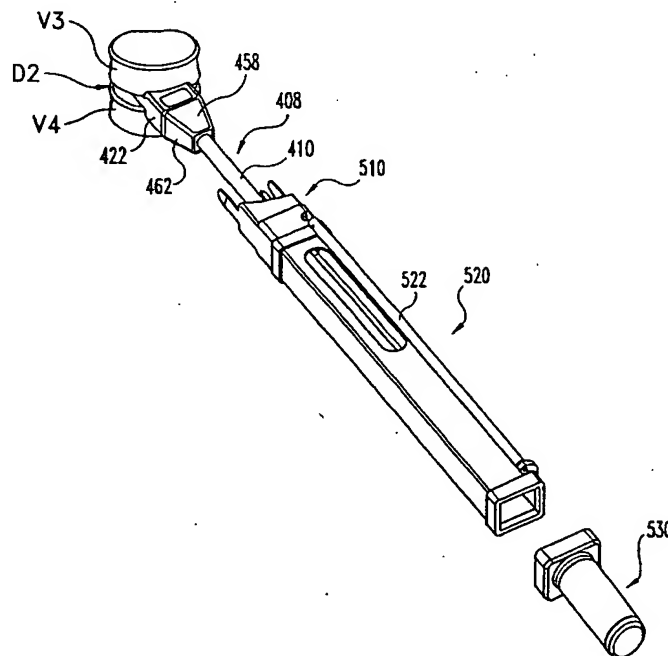
(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

[Continued on next page]

(54) Title: INSTRUMENTS AND TECHNIQUES FOR DISC SPACE PREPARATION



(57) Abstract: A series of instruments (30, 80, 120, 210, 510, 550) are provided for direct-anterior and oblique-anterior disc space and end plate preparation. The instruments (30, 80, 120, 210, 510, 550) provide precise guidance for channel formation in the vertebral endplates by guiding rotating and bladed cutting instruments (122, 250, 580). Instrumentation (550) for oblique-anterior disc space preparation includes compound angulation to account for the angle of approach to the spine and the angulation between adjacent vertebrae. Methods and techniques for use of the instruments (30, 80, 120, 210, 510, 550) are also described.

WO 01/62166 A3



— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(88) Date of publication of the international search report:
21 March 2002

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/05500

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/16 A61B17/17 A61B17/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>WO 98 04202 A (G.K.MICHELSON) 5 February 1998 (1998-02-05) cited in the application abstract page 24, line 6 - line 11; figure 2 page 35, line 22 - line 30; figures 18B-19 page 39, line 21 -page 40, line 15; figures 38,39,42 page 43, line 26 -page 44, line 4; figure 51 page 48, line 23 - line 27; figure 66 page 51, line 12 -page 52, line 22; figures 68-70,72</p> <p style="text-align: center;">--- -/-</p>	<p>1-6,9, 10,21,31</p>

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

2 January 2002

Date of mailing of the international search report

11. 01. 2002

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Nice, P

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/05500

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 571 109 A (R.BERTAGNOLI) 5 November 1996 (1996-11-05) column 9, line 5 - line 26; figures 1A-1B,5 column 8, line 51 - line 61; figure 3 ---	1,4,5, 11,31
A	US 5 486 180 A (T.L.DIETZ AND R.D.VANLANINGHAM) 23 January 1996 (1996-01-23) abstract; figures ---	1,4,9
A	US 5 772 661 A (G.K.MICHELSON) 30 June 1998 (1998-06-30) cited in the application column 1, line 21 - line 24 column 5, line 21 - line 28 column 19, line 49 - line 62 figures 7A,25,35 ---	1,11,21, 31
A	US 4 697 586 A (W.J.GAZALE) 6 October 1987 (1987-10-06) column 5, line 29 - line 31 column 5, line 47 - line 62 figures 1,7 ---	11-13,19
A	US 4 586 496 A (A.KELLER) 6 May 1986 (1986-05-06) column 1, line 5 - line 7 column 3, line 8 - line 44; figures 1-6 column 4, line 10 - line 19; figures 10,11 ---	11,13,14
A	WO 99 52453 A (SDGI HOLDINGS) 21 October 1999 (1999-10-21) figures 5A-5C ---	21-23,25
A	WO 99 52446 A (SDGI HOLDINGS) 21 October 1999 (1999-10-21) figures 11,13,15,16 ---	21-23, 25,31
A	US 5 803 904 A (H.MEHDIZADEH) 8 September 1998 (1998-09-08) abstract; figures 1,3,5 column 3, line 38 - line 42 ---	31,33
E	WO 01 28435 A (SDGI HOLDINGS) 26 April 2001 (2001-04-26) cited in the application page 10, line 23 -page 11, line 2; figures 22-24 -----	21-28

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 01/05500

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-10

Window assembly and pivotally linked guide assembly for a cutting piece for disc space preparation

2. Claims: 11-20

Cutting guide with channel adapted to receive a rib on a blade for disc space preparation

3. Claims: 21-30

Distractor with obliquely-angled leading edges for disc space preparation

4. Claims: 31-43

Distraction window with bone engaging surfaces with offset radius of curvature for disc space preparation

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 01/05500

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9804202	A	05-02-1998	US 6159214 A	12-12-2000
			AU 738161 B2	13-09-2001
			AU 3811797 A	20-02-1998
			EP 1006910 A1	14-06-2000
			JP 2000516114 T	05-12-2000
			WO 9804202 A1	05-02-1998
			US 2001000532 A1	26-04-2001
US 5571109	A	05-11-1996	DE 4328690 A1	02-03-1995
			AT 180157 T	15-06-1999
			CA 2129938 A1	27-02-1995
			DE 59408271 D1	24-06-1999
			EP 0641547 A2	08-03-1995
US 5486180	A	23-01-1996	US 5344423 A	06-09-1994
			AU 658466 B2	13-04-1995
			AU 3025492 A	12-08-1993
			CA 2086799 A1	07-08-1993
			DE 69306821 D1	06-02-1997
			DE 69306821 T2	26-06-1997
			EP 0554959 A1	11-08-1993
US 5772661	A	30-06-1998	JP 5269140 A	19-10-1993
			US 5484437 A	16-01-1996
			US 5015247 A	14-05-1991
			US 6080155 A	27-06-2000
			AU 707418 B2	08-07-1999
			AU 5025996 A	23-09-1996
			CA 2213827 A1	12-09-1996
			DE 29623247 U1	19-02-1998
			EP 0814718 A2	07-01-1998
			JP 11503339 T	26-03-1999
			WO 9627321 A2	12-09-1996
			US 5860973 A	19-01-1999
			AU 5025896 A	23-09-1996
			AU 7139994 A	03-01-1995
			AU 7741598 A	01-10-1998
			CA 2164859 A1	22-12-1994
			CA 2213819 A1	12-09-1996
			CN 1128944 A	14-08-1996
			DE 29623246 U1	02-01-1998
			EP 1092395 A2	18-04-2001
			EP 1093760 A2	25-04-2001
			EP 0703757 A1	03-04-1996
			EP 0812167 A2	17-12-1997
			JP 7008514 A	13-01-1995
			WO 9428824 A2	22-12-1994
			WO 9627345 A2	12-09-1996
			US 6210412 B1	03-04-2001
			US 5505732 A	09-04-1996
			US 6270498 B1	07-08-2001
			US 5797909 A	25-08-1998
			US 6096038 A	01-08-2000
			US 6149650 A	21-11-2000
			US 6264656 B1	24-07-2001
			US 6120502 A	19-09-2000
			US 5593409 A	14-01-1997
			US 5785710 A	28-07-1998

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 01/05500

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5772661	A		US 6123705 A	26-09-2000
			US 5741253 A	21-04-1998
			AT 169811 T	15-09-1998
			AU 3838789 A	12-01-1990
			CA 1332999 A1	15-11-1994
			DE 68928790 D1	24-09-1998
			DE 68928790 T2	25-03-1999
			EP 1153574 A2	14-11-2001
			EP 0419564 A1	03-04-1991
			EP 0712607 A2	22-05-1996
			US 6224595 B1	01-05-2001
			WO 8912431 A1	28-12-1989
			AU 706402 B2	17-06-1999
			AU 2129095 A	17-10-1995
			AU 4473899 A	11-11-1999
US 4697586	A	06-10-1987	NONE	
US 4586496	A	06-05-1986	DE 3560763 D1	19-11-1987
			EP 0157172 A1	09-10-1985
WO 9952453	A	21-10-1999	AU 739027 B2	04-10-2001
			AU 3488099 A	01-11-1999
			AU 3551899 A	01-11-1999
			AU 3744699 A	01-11-1999
			EP 1069862 A1	24-01-2001
			EP 1069864 A2	24-01-2001
			WO 9952446 A2	21-10-1999
			WO 9952447 A1	21-10-1999
			WO 9952453 A2	21-10-1999
			US 6241729 B1	05-06-2001
			US 6197033 B1	06-03-2001
			US 2001012942 A1	09-08-2001
			WO 9952446	A
AU 739027 B2	04-10-2001			
AU 3488099 A	01-11-1999			
AU 3551899 A	01-11-1999			
AU 3744699 A	01-11-1999			
EP 1069862 A1	24-01-2001			
EP 1069864 A2	24-01-2001			
WO 9952446 A2	21-10-1999			
WO 9952447 A1	21-10-1999			
WO 9952453 A2	21-10-1999			
US 6197033 B1	06-03-2001			
US 2001012942 A1	09-08-2001			
US 5803904	A	08-09-1998		
			JP 2001520906 T	06-11-2001
			WO 9921485 A1	06-05-1999
WO 0128435	A	26-04-2001	US 6277122 B1	21-08-2001
			AU 7878200 A	30-04-2001
			WO 0128435 A1	26-04-2001